Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (lcs)

FOLDER: K092090 - 424 pages

COMPANY: BYRNE MEDICAL INC. (BYRNMEDIA)

PRODUCT: ENDOSCOPIC INJECTION NEEDLE, GASTROENTEROLOGY-UROLOGY (FBK)

SUMMARY: Product: ERBELIFT HAND PUMP AND FLEXIBLE PROBE

DATE REQUESTED: Sep 18, 2012

DATE PRINTED: Sep 18, 2012

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K092090

Pg 1 of 4

510(k) SUMMARY

NOV 30 2009

Submitted By:	Byrne Medical Incorporated 3150 Pollock Drive Conroe, TX 77303 Tel: 936-539-0391 Fax: 936-539-2381
Contact Person:	Chris Hierholzer Quality Control Manager
Date Prepared:	April 22, 2009
Common Name:	Injector
Trade/Proprietary Name:	ERBELIFT™ Hand Pump and Flexible Probe
Classification Name:	Endoscopic Injection Needle (21 CFR Part 876.1500)
Product Code:	FBK
Legally Marketed Predicate Device:	Endoscopic Injection Needle 510(k) Number: K924102 and Endoscopic Injection Needle/Snare 510(k) Number: K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Pg 2 of 4

The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

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K 092090

Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has slightly different principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Byrne Medical, Inc.
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

NOV 30 2009

Re: K092090
Trade/Device Name: Erbelift Hand Pump and Flexible Probe
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: September 28, 2009
Received: September 29, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Indications for Use

510(k) Number (if known): K092090

Device Name: Byrne Medical, Inc.'s ERBELIFT™ Hand Pump and Flexible Probe

Indications For Use:

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092090

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Byrne Medical, Inc.
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

NOV 30 2009

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Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092090

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 03, 2009

BYRNE MEDICAL INC.
c/o INTERTEK TESTING SERVICES
2307 EAST AURORA ROAD UNIT B7
TWINSBURG, OHIO 44087
UNITED STATES
ATTN: DANIEL W. LEHTONEN

510k Number: K092090
Product: ERBELIFT HAND PUMP AND FLEXIBL

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Red the Safe Medical Devices Act of 1990 states that CDRH may not place

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

July 14, 2009

BYRNE MEDICAL INC.
c/o INTERTEK TESTING SERVICES
2307 EAST AURORA ROAD UNIT B7
TWINSBURG, OHIO 44087
UNITED STATES
ATTN: DANIEL W. LEHTONEN

510k Number: K092090

Received: 7/14/2009

Product: ERBELIFT HAND PUMP AND FLEXIBL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv .

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Telephone: +1 330-405-3552
Facsimile: +1 330-405-5518
www.intertek-etlsemko.com

09 Jul 2009

FDA CDRH DMC
JUL 14 2009
Received

CDRH Document Mail Center
Mailstop HFZ-401
Attention: THIRD PARTY REVIEW
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Third Party Review,

Enclosed is a Traditional 510(k), which has been reviewed by Intertek Testing Services NA, Inc. The technical reviewer and primary contact, should additional information be required, is:

Daniel W. Lehtonen Intertek Testing Services NA, Inc. 2307 E Aurora Rd. Unit B7 Twinsburg, OH 44087	Telephone: Fax: E-mail:	(937) 313-7454 (330) 405-5518 dan.lehtonen@intertek.com

Device and Submission Details

Project Number:	3179301
Date Received from Sponsor:	28 April 2009
510(k) Submitted by: **Address:**	Byrne Medical, Inc. 3150 Pollok Drive Conroe, TX 77303
Contact Name: **Title:** **Telephone No:** **Facsimile No:** **E-mail Address:**	Mr. Chris Hierholzer Quality Control Manager (936) 539-0391 (936) 539-2381 chierholzer@bymemedical.com
Device Proprietary Name: **Device Common or Usual Name:** **Device Classification Name:**	ERBELIFT™ Hand Pump and Flexible Probe Injector Endoscopic Injector Needle, Gastroenterology / Injector, Fluid, Non-electrically Powered
Classification Panel: **Regulation Number(s):**	Gastroenterology and Urology 21 CFR 876.1500 **Product Code(s):** FBK

Our recommendation is that the device is substantially equivalent to the legally marketed devices referenced in the review memo.

NOTE: For FDA convenience, a copy of the Final Indications for Use form and 510(k) Summary are located behind this letter.

Respectfully Yours,

Jay Y. Kogoma
Responsible Third Party Official

SD 1.4.1j (20Jul 2007) Mandatory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XVII. Recommendation

Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscopic Injector Needle, Gastroenterology / Injector, Fluid, Non-Electrically Powered
Regulatory Class:	II
Product Code:	FBK

Primary Third Party Reviewer:

Daniel W. Lehtonen — Date
Sr. Staff Engineer - Medical Devices

Responsible Third Party Official:

Jay Y. Kogoma — 09 Jun 2009 Date
Sr. Staff Engineer - Medical Devices

Branch Chief — Date

The following Appendices are attached to this review memo

SE Flowchart ..... Appendix A1.1
Written Communications in Reverse Chronological Order ..... Appendix A1.2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Indications for Use

510(k) Number (if known): _____

Device Name: Byrne Medical, Inc.'s ERBELIFT™ Hand Pump and Flexible Probe

Indications For Use:

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 150

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510(k) SUMMARY

Submitted By:	Byrne Medical Incorporated 3150 Pollock Drive Conroe, TX 77303 Tel: 936-539-0391 Fax: 936-539-2381
Contact Person:	Chris Hierholzer Quality Control Manager
Date Prepared:	April 22, 2009
Common Name:	Injector
Trade/Proprietary Name:	ERBELIFT™ Hand Pump and Flexible Probe
Classification Name:	Endoscopic Injection Needle (21 CFR Part 876.1500)
Product Code:	FBK
Legally Marketed Predicate Device:	Endoscopic Injection Needle 510(k) Number: K924102 and Endoscopic Injection Needle/Snare 510(k) Number: K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

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The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code.KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has slightly different principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 10993-1: 2003 Biological evaluation of medical devices, Part 1: Evaluation and testing

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993-1: 2003, Biological evaluation of medical devices, Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 14-228		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993-7: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	// 14-76	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
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Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

BMI Byrne Medical, Inc.
The Universal Irrigation Solution

3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

April 22, 2009

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

RE: Traditional 510(k): Byrne Medical, Inc. - ERBELIFT™ Hand Pump and Flexible Probe

Dear Intertek Reviewer,

Per agreement, three (3) original paper copies of the submission with one (1) having all original signatures are enclosed with an electronic copy.

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR Part 807, premarket notification is hereby made of the intention of Byrne Medical, Inc. to introduce into interstate commerce for commercial distribution ERBELIFT Hand Pump and Flexible Probe. This notification authorizes Intertek to submit this 510(k) to FDA as well as discuss the submission with the Agency.

See the CDRH Submission Cover Sheet for the 510(k)'s general elements and the Table of Contents for specific locations of the information in support of the elements. It was Byrne Medical's attention to have included all the necessary information to support the review. However if any more information is needed or questions arise, please feel free to contact the technical support person for the submission, Mr. John Tartal at 1-800-778-3723 Ext. 133.

Thank you in advance for your timely review.

Sincerely,

Chris Hierholzer
Quality Control Manager
Byrne Medical, Inc.

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MKT-012 Revision A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

THIRD PARTY CERTIFICATION STATEMENT

I, Jay Y. Kogoma, an employee of Intertek Testing Services NA, Inc. hereby and certify that for the Premarket Notification reviewed:

a) I continue to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA.

b) Statements made in my review as a third party are true and accurate to the best of my knowledge

c) My review is based on the 510(k) that I submitted with the review

d) I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Name: _____ Date: 05 MAY 2007

Printed Name: Jay Y. Kogoma

Title: Sr. Staff Engineer - Medical Devices

Intertek Testing Services NA, Inc.
2307 East Aurora Rd, Unit B7, Twinsburg, OH 44087
Telephone: 1-330-405-3552 Fax: 1-330-405-5518 Web: www.intertek-etlsemko.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

THIRD PARTY CERTIFICATION STATEMENT

I, Daniel W. Lehtonen, an employee of Intertek Testing Services NA, Inc. hereby and certify that for the Premarket Notification reviewed:

a) I continue to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA.

b) Statements made in my review as a third party are true and accurate to the best of my knowledge

c) My review is based on the 510(k) that I submitted with the review

d) I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Name: _____ Date: 06 MAY 2009

Printed Name: Daniel W. Lehtonen

Title: Sr. Staff Engineer - Medical Devices

Intertek Testing Services NA, Inc.
2307 East Aurora Rd, Unit B7, Twinsburg, OH 44087
Telephone: 1-330-405-3552 Fax: 1-330-405-5518 Web: www.intertek-etlsemko.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Ten (10) elevations were performed with the proposed needle-free elevation system and 10 with predicate needle injection system in a live porcine model (a >25 kg Yorkshire pig). The following data points were measured:

- Flow rate (ml/s)
- Perforation risk at maximum force

Note: The volume (1.5 ml) of saline for the in-vivo studies does not reflect the actual amount to be administered for the device use. This volume is selected solely to demonstrate the comparison between the proposed device and the predicate.

Results:

The results obtained from the ex-vivo and in-vivo tests are summarized below:

Parameters Tested	Proposed ERBELIFT (Needle Less group)	Predicate Carr Locke (Injection Needle group) K924102	Results / Statistical Analysis
Ex- Vivo Study			
Mucosal lift (independent of the endoscopist skill level)	Accomplished in 100% cases	Accomplished in 92% cases	Mucosal lift was accomplished in greater number of cases, using the proposed device
Perforations	None	-	Testing with the proposed device demonstrated no perforations
Ease of use (Simplicity)	in 92% cases	in 64% cases	$p = 0.02$ proposed device reported comparatively easier / simpler to use
Accuracy	< 3mm in 100% cases	3mm in 76% cases	$p = 0.01$ proposed device reported comparatively accurate
Height of elevation	15.27 ± 4.99 mm	15.84 ± 5.5 mm	$p = 0.72$ hence no statistical difference
Flow rate	0.61 ± 0.09 ml/s	0.53 ± 0.23 ml/s	$p = 0.1$ hence no statistical difference
Total procedure time	19.36 ± 3.35 sec.	28.2 ± 8.85 sec.	$p < 0.01$ use of proposed device resulted in comparatively lower procedure time

Questions? Contact FDA/CDRH/OCE/DID at CDRHEOMSTATUS@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Parameters Tested	Proposed ERBELIFT (Needle Less group)	Predicate Carr Locke (Injection Needle group) K924102	Results / Statistical Analysis
Maximum lift diameter	40.18±10.26 mm	33.03 ± 11.31 mm	p = 0.03 the maximum lift diameter was comparatively higher with the proposed device
In- Vivo Study			
Flow rate	0.39 ± 0.05 ml/s	0.36 ± 0.07 ml/s	p = 0.36 hence no statistical difference
Perforations (at maximum force)*	None	-	Testing with the proposed device demonstrated no perforations

* Based on input from the firm - In the in-vivo study one of the endpoints was "perforation at maximum force". In a discussion with the firm and confirmed by email the firm explained that in the in-vivo study one of the endpoints was "perforation at maximum force". In the conversation, this was defined as the maximum pull / activation force applied to the trigger of the hand pump by the user who is also deliberately ignoring the visual tissue effect – essentially simulating negligent use of the product. The purpose of this endpoint within the in-vivo study was to simulate if a perforation (worst case failure mode) of the tissue could occur when the device is not operated per the intended use - :i.e. if an untrained user, activates the trigger of the hand pump in a negligent manner (quick, strong pull force) in a thin walled tissue area, which does not require a high pull force to achieve a submucosal lift under direct visualization. The results were such that no perforations were caused.

Conclusion / Discussion:

The results show that the proposed needle-free system is comparable to the predicate in terms of flow rate and height of elevation. Also, the wall of the pig lumen is thin as compared to that of humans.

The distended bowel wall has a total thickness of 1.5 mm. Each layer (mucosa, submucosa and muscularis propria) is approx. 0.5 mm thick.

Since the ex-vivo / in-vivo tests showed no perforations in the pigs, there are no new concerns of safety / effectiveness for use in humans. The comparatively thicker lumen wall in the humans will withstand the mechanical force for saline induction with no greater risk of perforations than that of the predicate devise.

Overall, the proposed device functions as intended and there are no new safety or effectiveness concerns from performance standpoint. Therefore, the proposed device is substantially equivalent to the predicate in this regard.

Questions? Contact FDA/CDRH/OCE/DID at CDRHOIST@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XII. Performance Testing – Animal

The firm provided Animal Testing in Section III, Page 26 of the original submission. Please note that the ex-vivo and in-vivo studies discussed above (section XI of this Review Memo) were conducted on Yorkshire pigs and therefore they are representative of the Animal Testing. As discussed above, there is no impact on the safety or effectiveness of the device.

Therefore, the proposed device is substantially equivalent to the predicate in this regard.

XIII. Performance Testing – Clinical

N/A - No clinical data relied upon to determine substantial equivalence.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See Appendix A1.1 for the Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

   Same indication(s) statement

2. Explain why there is or is not a new effect or safety or effectiveness issue:

   NA

3. Describe the new technological characteristics:

   The new device utilizes "jet injection" technology rather than needle based injection. In the subject device, saline is forced through a blunt tipped probe having a 120 µm inner diameter that is in direct contact with the mucosal tissue, The force to the saline is generated by a hand pump in which a syringe containing saline is loaded. The saline is inducted through the mucosal layer (path of least resistance) into the submucosal tissue where the bleb forms.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

4. Explain how new characteristics could or could not affect safety or effectiveness:

   The new characteristics have the potential to impact both the safety and effectiveness of the device. The safety concerns related to perforation / laceration exist and the device's ability to generate acceptable polyp lift equivalent to that of the predicate is an effectiveness concern.

   To address these concerns the firm provided results from animal testing (ex-vivo and in-vivo testing) to demonstrate equivalent performance of the subject device to the predicate device. The results from the testing, as summarized on page 16 of this review memo, show that the subject device performed equivalently to the predicate and did not result in any tissue perforations or lacerations.

5. Explain how descriptive characteristics are not precise enough:

   NA - Descriptive characteristics are not precise enough to demonstrate that the proposed device can achieve submucosal elevations (polyp lift) comparable to that achieved with predicate needle system and without elevating the risk of perforations.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

   No new safety or effectiveness questions are raised with the change in technology to the subject device as compared to the predicate device. The safety concerns related to perforation / laceration exist and the device's ability to generate acceptable polyp lift equivalent to that of the predicate is an effectiveness concern. These are the same issues that the predicate device presented.

7. Explain why existing scientific methods can not be used:

   NA

8. Explain what performance data is needed:

   Performance / animal data is needed to demonstrate that the proposed device functions as intended and that it does not increase the risk of perforations. The following parameters: accuracy, flow rate, perforation risk, bleb diameter and height of submucosal elevation should be considered.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

   The ex-vivo and in-vivo animal tests demonstrate that the proposed device is comparable to the predicate (K924102) in terms of accuracy, flow rate, perforation risk, bleb diameter and height of submucosal elevation.

   Overall, the performance / animal data demonstrated that the proposed device functions as intended and the change in technological characteristic does not raise new concerns for safety or effectiveness of the device. Therefore, the proposed device is substantially equivalent to the predicate in this regard.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XV. Deficiencies

Item		Description of Deficiency
1.	**Location:**	**Missing – Standards Data Report for 510(k)s**
	Finding:	In Section I, Page 6 of your submission you make reference to standards EN 980 and ISO 11607-2. The FDA requires that Form 3654 be included with all 510(k) submissions that reference a national or international standard. A separate form is required for each standard referenced in the 510(k). Please complete the identified form for EN 980 and ISO 11607-2. The form is available on the FDA website at the following link: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf Note: Please reference the amendments (A1:1999 and A2:2001) in the standard title for EN 980.
	Response:	Form 3654 for ISO 14971, EN 980, 11607-02 (That is Standards in Section I, Page 6 in which Forms 3654 were not completed) were not submitted in the 510(k) for the Standards because the Form for these Standards cannot be accurately completed (Note: There is no test data, etc. involved with these standards.). These standards provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively. I have spoken with FDA regarding this matter and was told to use the Form and Summary Report for Standards in applicable situations. As requested amendments (A1:1999 and A2:2001) were included in the standard title for EN 980 on Section I, Page 6. See Exhibit 1.
	Closed Out:	06 Jul 2009 The firm indicated that in previous submissions to the agency, the agency FDA guided them to utilize the 3654 Form and Summary Reports for such standards in "applicable situations" and that the form was not needed for the referenced standards. Based on this, the firm did not include 3654 forms / summary reports for the ISO 14971, EN 980 and ISO 11607-2 standards. Additionally, the firm revised the title for EN 980 to include the amendments (A1:1999 and A2:2001). Section I, Page 6 (CDRH Coversheet) was revised to reflect this change. The response addressed the deficiency. See Item 2, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
2.	**Location:**	**Missing – Summary Reports**
	Finding:	In Section III, Pages 13-15, you have provided FDA Form 3654 for ISO 10993-1, ISO 11135-1 and ISO 10993-7. Per these forms, summary reports are stated to be provided. However, no such reports could be located in the submission. Please provide summary reports for the above mentioned standards to demonstrate the extent of conformance of these standards.
	Response:	A Summary Report was completed as Declaration of Conformance with Consensus Standards for each of the above Standards. See Page III-16 for ISO 10993-1. ISO 11135-1 and ISO 10993-7 are Standards that involve sterilization guidelines (i.e., EO validation and EO residuals). The Declaration of Conformance with Consensus Standards for ISO 11135-1 and ISO 10993-7 Standards were provided on Page III-17. Also, the involved Sterility Information regarding these Standards is provided on Page III-31. In the past, providing the Summary Reports in this manner was acceptable to FDA.
	Closed Out:	06 Jul 2009 The firm clarified the location of declaration of conformance and summary reports for the following standards: ISO 10993-1, ISO 11135-1 and ISO 10993-7. The declaration of conformance for ISO 11135-1 and ISO 10993-7 was provided on Page 17 of Section III of the original submission. A common summary report with Sterility information associated with these standards was provided on Page 31 of Section III of the original submission. Also, the compliance assessment and declaration of conformance for ISO 10993-1 was provided on Page 16 of Section III of the original submission. Additionally, the firm provided the MEM Elution report to demonstrate the Cytotoxicity testing for the proposed Flexible Probe. The response addressed the deficiency. See Item 4, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-OSTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
3.	**Location:**	**Section III, Page 4 – 510(k) Summary (Conclusions)**
	Finding:	You have stated that the technological characteristics of the proposed ERBELIFT system are 'similar' as compared to the predicates. However, in reviewing the submission the technological characteristics of the proposed needle less system are significantly different as compared to the predicates with needle system. Please update this section to state the technological characteristics as 'different' and provide a revised 510(k) summary.
	Response:	The conclusion was revised. See Exhibit 2. Note: The entire 510(k) Summary was provided in the Exhibit without the "Confidential" identifier so that it could be used for FDA's posting of the 510(k).
	Closed Out:	08 Jul 2009 The firm provided a revised 510(k) summary, without the "Confidential" identifier so that it could be used for FDA's posting of the 510(k). The "Conclusions" section of the summary was modified to identify the technological characteristics of the proposed device as "different" from the predicates. The response addressed the deficiency. See Item 3, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
4.	**Location:**	**Section III, Page 17 – Declaration of Conformance with Consensus Standards**
	Finding:	You have not listed the consensus standards ISO 14971, EN 980, ISO 11607-2 and ISO 10993-7 in the 'Declaration of Conformance'. However, these standards have been identified in the Utilization of Standards page of the CDRH Cover Sheet (Section I, Page 6). Please provide a revised 'Declaration of Conformance with Consensus Standards' identifying all applicable standards or include rationale as to how the standards are used.
	Response:	ISO 10993-7 was included as a Declaration of Conformance with Consensus Standards on Page III-17. Again, ISO 14971, EN 980, ISO 11607-2 are Standards that provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively; therefore, Declaration of Conformance with Consensus Standards for these Standards is not applicable.
	Closed Out:	06 Jul 2009 In reviewing the response, the firm clarified that ISO 10993-7 was included in Declaration of Conformance (Section III, Page 17 of the original submission). The additional standards: ISO 14971, EN 980 and ISO 11607-2 provide guidance for risk analysis, using international symbols on labeling, and validating packaging, respectively. Therefore, the firm stated that the Declaration of Conformance for these additional standards is not applicable. See close out comment for Item #1 of this report relating to completion of form 3654 for the additional standards noted. The response addressed the deficiency.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
5.	**Location:**	**Section III, Page 19 – Biocompatibility Testing**
	Finding:	You have provided a summary of biocompatibility for individual materials of the proposed device. For biocompatibility assessment, FDA recommends that the test articles be extracted from the finished, sterilized device. Also, there may be possible contamination while assembling the device. Please explain as to how the data provided demonstrates the biocompatibility of the finished sterilized device. Alternatively, please provide a revised biocompatibility testing for the final finished device. Per, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the following tests are recommended for the proposed device: Cytotoxicity, Sensitization and Irritation (or Intracutaneous Reactivity). The compliance assessment and the basis provided for individual materials are not adequate to justify the omission of Sensitization and Irritation tests. Please provide a detailed explanation as to how the omission of these tests will not affect the biocompatibility of the finished device. Alternatively, please provide biocompatibility reports for Sensitization and Irritation tests. Please reference the standard* as applicable for specific tests and ensure that all the test reports follow the extent of regulation of respective standard. Also, please include a separate form 3654 for additional standards (if any) that are referenced in the submission. *Per the FDA website, ISO 10993-10 is the recommended biocompatibility standard for irritation and delayed-type hypersensitivity tests. Also, per extent of regulation for ISO 10993-1, ccompliance with FDA Good Laboratory Practices (GLPs) regulation is required. Please revise the biocompatibility section to indicate that the testing is done in accordance with GLP guidelines. Additionally, there are references to the cytotoxicity and biocompatibility risk assessment reports in the submission; however no such reports could be located. Please provide these reports, since they are necessary for assessing biocompatibility. Note: Please revise the Utilization of standards list in the CDRH Coversheet and the Declaration of Conformity to reflect the identification of additional standards.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	The materials for the Flexible Probe were chosen based upon their long history of biocompatibility as well as their use in medical applications (e.g., many disposable medical instruments, catheters, shunts, etc. use these materials.). Our initial assessment of the need to only perform Cytotoxicity was confirmed by a Biocompatibility Risk Assessment generated by an independent expert (Dr. Bill Bradbury). See Exhibit 3.1. Prototype samples (Note: The entire Flexible Probe) were prepared by our contract manufacturer using the same manufacturing processes that will be employed for the finished medical device. These samples were sent to a contract testing laboratory. The Flexible Probes were sterilized (sterilization representing greater than 2X) and then the Cytotoxicity (MEM Elution) testing was performed. Reactivity was "0" (Note: Sterilization and Testing was done under GLP.). See Exhibit 3.2.
Closed Out:	08 Jul 2009 The compliance assessment for ISO 10993-1 was provided earlier, in Section III, Page 16 of the original submission. Additionally, the firm provided the Biocompatibility Risk Assessment generated by an independent expert (Dr. Bill Bradbury) to address the biocompatibility of the direct / indirect patient contacting materials. The report provided information regarding the long history of their biocompatibility as well as their use in medical applications (e.g., disposable medical instruments, catheters, shunts, etc.). Additionally, the firm provided material specification sheets for all the direct / indirect patient contacting materials (PEEK, Nylon 11, titanium dioxide, Genesolv S-T solution, Colorcon MD-1185 and Colorcon MD-1120). Based on the history of safe use of these materials and the firm's biocompatibility compliance assessment, the omission of Sensitization and Irritation tests is justified. Also, the firm provided MEM elution report to demonstrate the cytotoxicity testing of the Flexible Probe. The results demonstrated that the materials are non cytotoxic. Additionally, the firm stated that the biocompatibility testing was performed on the final finished sterile Flexible Probe and as per GLP guidelines. Therefore, based on the compliance assessment, the expert report from Dr. Bill Bradbury and the cytotoxicity testing (MEM Elution) report, there are no new concerns impacting safety / effectiveness from the biocompatibility standpoint. The response addressed the deficiency. See Items: 4 & 5, Sub-Tab 01Jul2009 and Item 3, Sub-Tab 07Jul2009, Tab 7 of the Review Binder for details.

M0

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
6.	**Location:**	**Section III, Page 20 – Materials Used**
	Finding:	Per FDA Guidance Document for the Traditional 510(k) dated August 12, 2005, it is recommended that adequate material information be provided for all the device components that come into direct or indirect contact with the patient. Please provide material designation and manufacturer information for the following materials: Nylon 11 (Clear) and Nylon 11 (White). Also, please clarify the model number of Polyetheretherketone (PEEK) and provide material specifications sheet for the Colorcon MD-1185 and Colorcon MD-1210. Additionally, please identify the K number of the control syringe intended to be used as an accessory with the proposed device.
	Response:	As provided in the biocompatibility study (See Page III-20) , PEEK, Nylon 11 White, Genesolv S-T (Solvent), and Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer) are the materials that have the potential of indirect and/or direct patient contact (Note: Not Nylon Clear). The requested additional material information is as follows: PEEK: Victrex® *PEEK* Type 381G, Natural [Material Safety Data Sheet (MSDS) CAS#31694-16-3 – 381G] {See Exhibit 4.1} Nylon 11 White: Elf Atochem North America Nylon 11 (Clear) [MSDS CAS# - 25587-80-8 - Part # 0096 – Medron] with Whittaker, Clarke, and Daniel Inc. 0.9 wt.% Titanium Dioxide (TiO_2) [MSDS CAS # 13463-67-7] {See Exhibit 4.2} Genesolv ST (Solvent): Honeywell Genesolv S-T [MSDS] {See Exhibit 4.3} Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer): Colorcon Black Ink (MD-1185) & Colorcon Reducer (MD-1210) [MSDSs] {See Exhibit 4.4} ***Note: For additional information in regards to materials of the device and as well as indirect and direct patient exposure reference Page IV-5 (Device Drawing), Pages III-18 to III-26 (Biocompatibility Study) and Exhibit 3.1 (Biocompatibility Risk Assessment by Independent Expert Dr. Bill Bradbury)*** Control Syringe: Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings); 510(k) Number K920135

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
	Closed Out:	06 Jul 2009 The firm identified the model number of Polyetheretherketone (PEEK) as Victrex® *PEEK* Type 381G, Natural. Also, the firm provided material specification sheets for the all the direct/ indirect patient contact materials, namely PEEK, Nylon 11, Genesolv S-T solution, Colorcon MD-1185 and Colorcon MD-1120. Additionally, the K number for the control syringe was identified as K920135 (Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings). The response addressed the deficiency. See Item 5, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
7.	**Location:**	**Missing – Contraindications (Instructions for Use Manual: Proposed Labeling)**
	Finding:	Per labeling provided on Page 4, the use of the predicate K924102 is contraindicated for uncooperative patients and/or patients with severe coagulopathy. Also, as stated on Page 23, the contraindication for the predicate K040961 include those specific to any endoscopic procedure, uncooperative patients, and patients with coagulopathy. In reviewing the Instructions for Use Manual for the proposed device, there are no contraindications provided. Please provide revised labeling with the contraindications included or provide a rationale explaining why you feel the contraindications are not applicable to your device.
	Response:	The statement, "Contraindications: The use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy.", was added to the labeling (Instructions For Use). See Exhibit 5.
	Closed Out:	06 Jul 2009 The firm provided revised Instructions for Use manual, including the following contraindication: "the use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy." The response addressed the deficiency. See Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
8.	**Location:**	**Section V, Pages 32 – Safety Precautions / Warnings**
	Finding:	The predicate labeling provided for comparison contains precautions / warnings specific to endoscopic procedures and handling of the device. However, the proposed labeling does not include these warnings / precautions. Since, the proposed device employs a comparable endoscopic procedure (except for needle injection), please revise the labeling to include relevant warnings / precautions.
	Response:	I have meticulously reviewed the "Warnings and Precautions" in the labeling of the predicates for statements which are applicable in our labeling. I find that I have included all necessary statements as "Safety Instructions- Warnings" as follows: Training, not using damaged product, not using product in which there may be a package integrity issue, not using product beyond its expiration, etc. (Note: All of these statements were considered as a result of our risk assessment.). Many statements in the "Warnings and Precautions" for the predicate devices actually do not belong in the section (e.g., the device being single use, compatibility of working channel scope size, solution types, etc.). The information is instructional in nature and diminishes the effectiveness of the "real" Warnings and Precautions in the predicate labeling. Therefore, as directed by FDA, some of the statements in the predicate labeling Warnings and Precautions section are included in our labeling but not in our "Safety Instructions- Warnings" section.
	Closed Out:	06 Jul 2009 In reviewing the response, the safety warnings and precautions, as applicable for any endoscopic procedure, were incorporated in the Instructions for use manual. They have not been discussed in a separate section. Instead, they are included within the directions for use of the proposed device. The response addressed the deficiency.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHOCEDIDFollowUps@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
9.	**Location:**	**Section V, Pages: 34 & 35 – Marketing Statements / Claims**
	Finding:	The marketing statements / claims for the proposed device state: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe, especially with wet gloves. The information provided in the submission does not support any of the above mentioned claims. Please remove these claims or provide scientific explanation to substantiate them. Please note that claims of this nature typically require clinical data for substantiation. If such data is needed, the device will not be eligible for 3rd Party Review and will need to be withdrawn and submitted directly to FDA. Also, on Page 35, you claim that "in larger working channel scopes, the Probe may be able to be passed down alongside another instrument." Please provide a scientific discussion and supporting information as to how the integrity of the probe will remain unaffected with the presence of another instrument within the working channel. Alternatively, please remove this claim and revise the section.
	Response:	Substantiation of Claim: "***An easier and less demanding method of generating force to drive the fluid into the submucosa.***" Pulling the trigger of the ERBELIFT Hand Pump ergonomically designed pistol grip hand pump allows for less activation force to push the plunger of the syringe compared to an in-line motion like when the user uses their hand force applied to syringe connected to an injection needle. Substantiation of Claim: "***Flexible Probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe.***" The winged luer lock on the ERBELIFT Flexible Probe provides more surface area for the user's fingers to grasp onto when twisting the luer to lock or unlock – this additional winged surface area is not available on standard leur locks used on the injection needles. Note: "***especially with wet gloves***" was removed from the statement. See Exhibit 6. **"In larger working channel scopes, the Probe may be able to be passed down alongside another instrument."** was removed from the list. See Exhibit 6.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
	Closed Out:	06 Jul 2009 The firm provided adequate information to substantiate the following marketing statements / claims: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe (Note: the phrase "especially with wet gloves" was removed from the statement) Also, the claim "In larger working channel scopes, the Probe may be able to be passed down alongside another instrument" was removed from the submission. The response addressed the deficiency. See Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
10.	**Location:**	Throughout Submission - Classification Identification
	Finding:	The classification for the device is identified as 876.1500 (FBK) and / or 880.5430 (KZE). Please revise all documents (e.g. CDRH cover sheet, summary, etc.) to identify the classification as the 876.1500 (FBK) or revise to include both classifications and a detailed discussion supporting the classification designation.
	Response:	All documents in the submission were changed to identify the device's classification as only 876.1500 (FBK). See Exhibit 7 (Also Exhibit 2).
	Closed Out:	08 Jul 2009 The firm identified the proposed device classification as 876.1500 (FBK) and revised the affected pages (of the CDRH Coversheet, Form 3674 and submission summary) to reflect this change. The response addressed the deficiency. See Item 7, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
END		

XVI. Contact History

See Appendix A1.2 for copies correspondence between third party and the firm.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-DISTATUS@fda.hhs.gov or call 301-796-8118.

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Premarket Notification [510(k)] Review
Traditional/Abbreviated
K_____

Date:	09 Jul 2009		
To:	The Record	Office:	
From:	Daniel W. Lehtonen Intertek Testing Services NA, Inc. 3rd Party Review Memo	Division:	

510(k) Holder:	Byrne Medical, Inc.
Device Name:	ERBELIFT™ Hand Pump and Flexible Probe
Contact:	Mr. Chris Hierholzer
Phone:	(936) 539-0391
Fax:	(936) 539-2381
E-mail:	chierholzer@byrnemedical.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce (ERBELIFT™ Hand Pump and Flexible Probe) into interstate commerce.

The proposed ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. The proposed system encompasses following design changes as compared to the predicates cleared under K040961 and K924102

- The Hand Pump is included as an additional component for the proposed device to provide mechanical force to the syringe used for saline delivery as compared to the predicates with needle injection system which only utilized a syringe.
- The working diameter (1.3 mm) of the ERBELIFT Flexible Probe is smaller as compared to the sheath working diameter (2.5 / 3.0 mm) for the Carr Lock Injection Needle System / I-Snare System predicates. Also, the ERBELIFT Flexible Probe tip has a smaller inner diameter of 0.120 mm as compared to the predicate 25 G needle tip with an outer diameter of 0.508 mm and an inner diameter of 0.241 mm used with the predicates.
- The materials used for the Flexible Probe and Hand Pump are different compared to the predicates. The Flexible Probe is made of Nylon and stainless steel, whereas the Hand Pump is made of Polyetheretherketone (PEEK) and Nylon. Medical grade inks / reducer are used to imprint logos on the Probe. Additionally, a Genesolv S-T solvent is used to clean the Probe tip prior to treatment.

Overall, the technological characteristics of the proposed device are different as compared to the predicates that utilize a needle for injection. However, these technological characteristics are comparable to that of the needle-free injection devices or jet injectors for the same intended use. Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHREGSTATUS@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

The proposed system employs a needle-free mechanism and does not puncture the tissue. Instead, the combination of the force of the saline applied via the Hand Pump / syringe combination and the placement of the flexible probe enables for the saline to be inducted through the tissue and disperse into the submucosal layer. This process allows the user to achieve their desired polyp lift. The pressure and flow rate of saline delivery depend upon the speed with which the Hand Pump handle is squeezed (the more times the users squeezes the handle over a given time the higher the pressure and flow rate). However, each squeeze of the handle delivers 0.75 ml (approx.) saline, thus the user has control of how much saline is being delivered.

The materials used for the proposed system have a history of safe medical use and the firm provided adequate biocompatibility testing to substantiate these material changes (as summarized in Section VIII of this Review Memo). Also, the firm provided ex-vivo and in-vivo performance testing (animal based) to demonstrate the efficacy of the proposed device in comparison to the predicate K924102. The performance data showed the device provides equivalent performance to the predicate with no increased safety concerns. Based on the information provided, the design / material changes do not raise any new questions in terms of safety or effectiveness of the proposed device.

Therefore, based on the information provided by the firm's submission, the ERBELIFT Hand Pump and Flexible Probe is substantially equivalent to predicate devices cleared under K040961 and K924102, with respect to indications for use, performance, and labeling and that the technological changes do not introduce new safety or effectiveness questions as shown in the firm's submission and summarized in this review memo.

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: **Prescription Use**)	Before submission TOC	X		
Truthful and Accuracy Statement	Section II, Page 1	X		
510(k) Summary or 510(k) Statement	Item 2, Sub-Tab 07Jul2009, Tab 7	X		
Standards Form	Section III, Pages 13-15	X		

Note: Reference to "Tab 7" in the above table refers to the 3rd Party Review Binder. Section numbers refer to the firm's original submission.

The above administrative documents were provided by the sponsor and found to meet the FDA requirements at the present time.

A copy of the final Indications for Use Form and a copy of the final 510(k) Summary are located behind the 3rd Party Submission Cover Letter in Tab 1 and copies of FDA form 3654 for all standards referenced in the submission are located in Tab 2 of the Third Party Review Binder.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X*	X*	
Is the device reusable (not reprocessed single use)?	X*	X*	
Are "cleaning" instructions included for the end user?	X		

* The proposed ERBELIFT system consists of a Hand Pump and a Flexible Probe. The Hand Pump is reusable and provided non-sterile, whereas the Flexible Probe is labeled for single use and provided sterile. Adequate cleaning and reprocessing instructions for the Hand Pump are provided in the Instructions for Use Manual (see Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder).

DCD

The ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe (previously cleared under K920135) is intended to be used as an accessory with the proposed device; however it is not provided with the device. The syringe is filled with sterile normal saline and is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Probe is primed with the saline and then its distal end is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target (submucosal) tissue without puncturing the mucosa. The handle of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the submucosal bed of the polyp or lesion to achieve a desired tissue lift.

Device Component	Specification	
	Dimensions	**Materials**
Hand Pump	Length: 8-3/4" (22 cm) Thickness: 2-1/2" (6 cm) Width: 6" (15 cm)	Nylon and stainless steel
Flexible Probe	Length: 260 cm Outer Diameter: 1.3 mm Inner Diameter (jet stream): 0.120 mm (120 µm)	Polyetheretherketone (PEEK) and Nylon (Medical grade inks and reducer are used to imprint logos on the Probe)

The Hand Pump is a gun-shaped component with a handle and a barrel (Slot for Mounting a Syringe). It is reusable and delivers approximately 0.75 ml of normal saline per squeeze of the handle. The Flexible Probe consists of a handle with a standard Luer lock connection hub and catheter (tubing). Its distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 µm. It is provided as sterile and labeled for single use. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute. The pressure and flow rate depend upon the number of times the handle is squeezed.

Note: The firm provided product pictures and engineering drawings for the proposed ERBELIFT Hand Pump and Flexible Probe, which can be located in Section IV of the original submission.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

IV. Indications for Use

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Discussion: The Indications for Use of the proposed ERBELIFT Hand Pump and Flexible Probe are comparable to that of the predicates. Like the predicates, the function of the proposed device is the same in that the devices are intended for the delivery of fluids into the submucosal tissue for endoscopic purposes. The lifting medium (sterile normal saline) is a part of the types of solutions identified for use with the predicates. There are no new indications.

Therefore, the proposed device is substantially equivalent to the predicates in this regard.

V. Predicate Device Comparison

The firm identified the following predicate devices:
K924102 [Cleared 25 Nov 1992], K040961 [Cleared 08 Jul 2004]

The firm has provided a comparison table in **Section III (Pages: 5-10)** of the original submission (as shown in the below table). Review of the comparison tables show that the new device has the same characteristics as the predicate devices and supports the sponsor's claims.

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Manufacturer and 510(k) Applicant	United States Endoscopy Group, Inc.	United States Endoscopy Group, Inc.	Byrne Medical, Inc.
510(k) Number	K924102	K040961	TBD

ULDB ULDB

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	K924012 Injection Needle	K040961 Injection Needle/Snare	
Indications For Use	Intended Use in 510(k)*: The U.S. Endoscopy needle is indicated for use with flexible gastoscopes, colonoscopes, sigmoidoscopes, duodenoscopes, choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of fluids or tissue and for injection of medications or dyes into tissue.	Intended Use in 510(k)*: The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.	The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.
Materials			
Hand Pump	Not Applicable	Not Applicable	Plastic and Stainless Steel
Needle or Probe	Plastics, Teflon, Metal, Stainless Steel	Plastics, Metal, Stainless Steel	Plastics and Medical Grade Inks with Reducer
Physical Characteristics			
Hand Pump	Not Applicable	Not Applicable	A Gun Shaped Device with a Handle and a Slot for Mounting a Syringe
Needle or Probe	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle and Snare	Handle with a Standard Luer Lock Connection Hub and Catheter (Tubing)

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Dimensions			
Hand Pump	Not Applicable	Not Applicable	Barrel Length: 8-3/4" (22 cm) Width (Top of Barrel and Handle): 6" (15 cm) Thickness (Width of Barrel): 2-1/2" (6 cm)
Needle or Probe	Working Length: 230 cm Working Outer Diameter (O.D.): 2.5 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm	Working Length: 230 cm Working Outer Diameter (O.D.): 3.0 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm Snare Maximum Extension Width: 2.5 cm	Working Length: 260 cm Working Outer Diameter: 1.3 mm Tip Inner Diameter/ Stream: 0.120 mm/ 120 µm
Force / Flow Rate	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	145 to 650 psi / 17 to 38 ml/minute

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Labeling			
Hand Pump	Not Applicable	Not Applicable	Carton Label and Instructions For Use
Needle or Probe	Outer Packaging Labels and Instructions For Use	Outer Packaging Labels and Instructions For Use	Outer Packaging Pouch, Carton, and Case Labels as well as Instructions For Use
Condition Provided/ Use Condition			
Hand Pump	Not Applicable	Not Applicable	Non-sterile/ Reusable
Needle or Probe	Sterile/Disposable-Single Use	Same	Same
Sterilization Method Used by Manufacturer			
Hand Pump	Not Applicable	Not Applicable	Not Sterilized
Needle or Probe	Ethylene Oxide	Same	Same
Cleaning/Disinfection			
Hand Pump	Not Applicable	Not Applicable	Method in Notes On Use
Needle or Probe	Not Applicable	Same	Same
Required Accessory	Syringe	Syringe	Syringe [Not included with the device - Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings); 510(k) Number K920135]

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Delivered Medium/ Solutions	Medicinal Sub-stances and Solutions as Follows: Sodium Morrhuate, Sodium Tetrade-cylsulfate, Ethy-nolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotrad-ecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Medicinal Sub-stances and Solutions as Follows: Sodium Morrhuate, Sodium Tetrade-cylsulfate, Ethy-nolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotrad-ecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Sterile Normal Saline Note: Also, referred to as 0.9%NaCl or Physiological Saline. It is a specific concentration of "Hypertonic Saline".
Target Population	Endoscopic Patient Candidates with Polyps or Mucosal Lesions	Same	Same
Anatomical Site	Esophagus, Stomach, Duodenum, Small Intestine, and Large Intestine	Same	Same
FDA Guidance Documents Used	Unknown	Unknown	Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s, 8/12/05

The following major differences were identified from the device to the predicate(s). A justification of how these differences is determined that the device is substantially equivalent to the predicate is also provided. All other differences are considered minor and a justification is not required.

1. The Hand Pump is included as an additional component for the proposed device to provide mechanical force for saline delivery (fluid induction method) as compared to the predicates with needle injection system.

2. The working diameter (1.3 mm) of the ERBELIFT Flexible Probe is smaller as compared to the sheath working diameter (2.5 or 3.0 mm) of the predicates.

3. The ERBELIFT Flexible Probe tip has a smaller inner diameter of 0.120 mm as compared to the predicate 25 Ga. needle tip with an outer diameter of 0.508 mm and an inner diameter of 0.241 mm. The working length of the Probe is 260 mm.

   Discussion: The predicates (K040961 and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. For the propsoed device with a needle-free system, the Hand Pump is included to provide the force to the control

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syringe for inducing the pressurized fluid into the submucosa to achieve desired lift. This technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

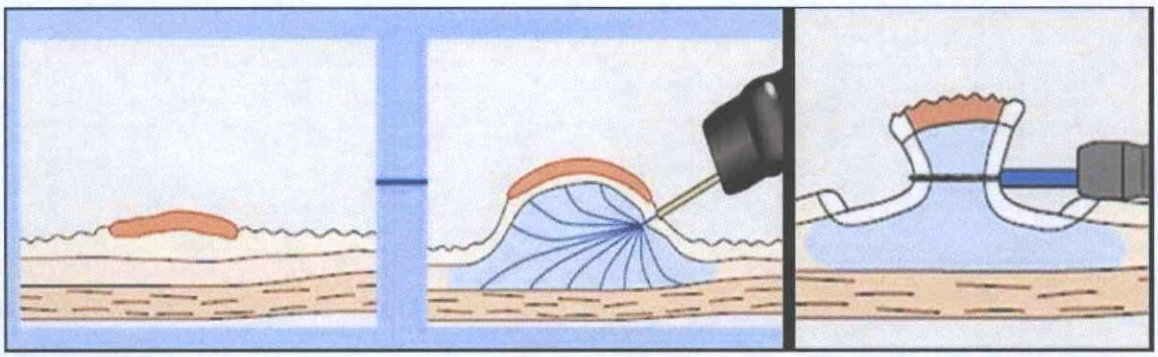

Fig 1: Schematic of submucosal elevation achieved using ERBELIFT Flexible Probe & Hand Pump

While the predicates employ needle system to puncture and penetrates the tissue, the proposed device Probe is not intended to puncture the mucosa. Instead, the Probe is placed against the mucosa and the hand pump handle is squeezed. With each squeeze of the handle, a fixed volume of saline is released from the control syringe. The release of saline in the GI tract results in the expansion of the surrounding tissues. However, within the GI tract, the mucosa, muscularis proproa and the serosa do not retain the saline and hence do not allow for the formation of saline bleb (localized collection of the fluid). Also, since the fluid property is to seek the path of least resistance, the saline travels to the aerolar tissue of the submucosal layer. The submucosa is a dense irregular layer of connective tissue with large blood vessels, lymphatics and nerves and is located beneath the mucosa. It allows for the dispersion of saline and hence leads to formation of a bleb of saline in the polyp bed. This bleb formation results in a marked elevation of the polyp and thereby creates the lift (See Fig. 1).

The smaller outer diameter and fluid stream of the ERBELIFT Flexible Probe causes less penetration damage to the tissue as compared to predicates. With the amplified force from the Hand Pump, the saline disperses in the submucosa without actually puncturing the mucosal tissue. Therefore the chances of complications like bleeding and laceration are comparatively reduced as compared to the predicates. Also, the Performance (ex-vivo and in-vivo animal tests) results demonstrated that there were no perforations with the use of proposed device (see Section XI of this Review Memo). Further, the working length of the flexible probe (260 mm) is comparable to that of the predicate needles (230 mm). The design of the Hand pump and the fixed volume of the saline (0.75 ml per squeeze of the handle) limit to allow the user to control the saline delivery volume.

Therefore, the modifications of having a Hand Pump as well as a Flexible Probe (with a smaller working diameter and tip configuration) do not raise any new concerns or impact the safety or effectiveness of the device.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

4. The materials used for the Flexible Probe and Hand Pump are different compared to the predicates.

   Discussion: The proposed device flexible probe is made of Nylon and stainless steel, whereas the hand pump is made of Polyetheretherketone (PEEK) and Nylon. Additionally, Medical grade inks / reducer are used to imprint logos on the Probe and the Genesolv S-T solvent is used to clean the Probe tip.

   The firm provided adequate biocompatibility data (including the material specification sheets and test reports, as summarized in Section VIII of this Review Memo) to substantiate the change and there is not impact on safety or effectiveness of the device.

VI. Labeling

The firm provided labeling for the proposed device which can be located in **Section V (Pages: 29-31)** of the original submission. The final version of the Instructions for Use manual can be located in Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder.

Overall, the labeling contains the following:

- Intended Use Statement
- Directions for Use
- Relevant Contraindications, Warnings, and Precautions
- Prescription Use Statement
- Marketing statements / claims

The Hand pump is a reusable component of the proposed device. It can be reused for up to 100 procedures and is required to be cleaned by wiping with water and hospital grade disinfectant prior to each use.

Overall, the proposed device labeling provides adequate information for operating and reprocessing the device. Adequate justification has been provided for the marketing claims and statements. The user manual also outlines the steps for the device preparation and its usage with the endoscope.

Additionally, the firm provided predicate user manuals (see Section V of the original submission, Pages: 1-28 for details) for comparison with the proposed device labeling. Review of predicate labeling does not raise any new concerns that would impact the safety / effectiveness of the proposed device.

Therefore, the proposed device is substantially equivalent to the predicates in this regards.

VII. Sterilization/Shelf Life/Reuse

The firm provided sterilization information for the proposed device, which can be located in **Section III, Page 31** of the original submission.

The proposed ERBELIFT system consists of a Hand Pump and a Flexible Probe. The Hand Pump is reusable and provided non-sterile, whereas the Flexible Probe is labeled for single use and provided sterile. The Sterilization Validation was carried out per the standard method described in ANSI / AAMI / ISO 11135-1:2007. The method used is Ethylene Oxide sterilization and the Sterility Assurance Level (SAL) is stated as 10^{-6}.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

The Probe is placed in a protective sheath and then packaged in a Tyvek Pouch, suitable for Ethylene Oxide sterilization and designed for maintaining its integrity. The firm has stated that the ethylene oxide residual levels will be evaluated per AAMI / ANSI / ISO 10993-7:1995 and that prior to the distribution of the ERBELIFT Flexible Probe, the residual levels for each product will not exceed the following:

Ethylene Oxide (EO)	Ethylene Chlorohydrin (ECH)
20 mg in the first 24 hours	12 mg in the first 24 hours

There are no new concerns from the sterilization standpoint. Therefore, the proposed device supports the substantially equivalent determination in this regard.

VIII. Biocompatibility

Biocompatibility information is included in **Section III, Page 18** of the original submission. The proposed ERBELIFT Flexible Probe is categorized as being in limited contact (<24 hours) with gastrointestinal tissue during Endoscopic Surgery (Note: Contact time ranges from a few seconds to five (5) minutes).

The firm provided compliance assessment for ISO 10993-1 in Section III, Page 16 of the original submission. Additionally, an expert report from Dr. Bill Bradbury was provided to address the biocompatibility of the direct / indirect patient contacting materials. The report provided information regarding the long history of their biocompatibility as well as their use in medical applications (e.g., disposable medical instruments, such as catheters and shunts). The report can be located in Item 4, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder.

The firm provided MEM elution report to demonstrate the cytotoxicity testing of the Flexible Probe. The results demonstrated that the materials are non cytotoxic.

Material (including adhesives)	Summary of Testing
Victrex Polyetheretherketone (PEEK)	MEM Elution Test (Cytotoxicity Testing) Cell Line: Mouse Hetroploid Connective Tissue (L-929) Incubation Period: 72 ± 3 hours at 37 ± 1 °C Amount tested / Sample extract: 200.5 cm^2 / 66.8 mL Result: Non cytotoxic
Nylon 11 (white)	
Colorcon MD-1185 No-Tox Black Ink and Colorcon MD-1210 Reducer	
Genesolv-ST Solvent	See Item 4, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder for details

Note: the firm stated that the biocompatibility testing was performed on the final finished sterile Flexible Probe and as per GLP guidelines.

Below is the summary of the component materials that are intended for direct and indirect patient contact.

Victrex PEEK (Polyetheretherketone)
The Catheter Shaft and the tip of the Flexible Probe are made of Victrex PEEK, which is the same material used for the Catheter Shaft of the ERBEJET2 Flexible Probe (previously cleared under K072404). The Probe tip may come in brief contact with the tissue compromised during injection of the saline, however; it is not intended to penetrate the tissue. The Shaft passes through a lumen in

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the endoscope and only a couple of centimeters of the shaft and the tip, exiting the distal end of the endoscope, will have direct contact with the gastrointestinal mucosal tissue.

Nylon 11 (White)
The Luer Hub is made of white Nylon 11 and is over-molded onto the proximal end of the 260 cm long catheter shaft. The Hub and strain relief are on the outside of the proximal end of the Probe and have no direct contact with gastrointestinal tissue of the patient. The inner lumen of the Hub has indirect contact through the normal saline that passes through the Probe and is force-induced into the tissue. A material specification sheet has been provided for Titanium dioxide, which is a pigment added to form Nylon 11 (White).

Colorcon Black Ink (MD-1185) & Colorcon Reducer (MD- 1210)
They are used to print the ERBE Logo on the distal tip of the Probe and hence have a direct contact with the gastrointestinal mucosal tissue.

Genesolv-ST solution
It is used to clean a portion of the distal tip of the Probe, prior to printing and hence will have a direct contact with the mucosal tissue.

The firm provided material specification sheets for the above mentioned direct / indirect patient contacting materials which can be located in Item 5, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder.

Note: The strain relief for the Probe is made of Nylon 11 (clear), which is a non-patient contacting material. The Genesolv-ST cleaner, Colorcon MD-1185 black ink, and Colorcon MD-1210 reducer have a history of safe use (e.g. with Medron Inc.'s processing of BARD Access System Catheters such as Groshong & PerQ-Cath Medline Catheters and Power Pic Solo Catheters).

The above information supports the biocompatibility and safe patient use for the ERBELIFT Flexible Probe. There is minimal to no-risk of adverse biocompatibility concerns from the 5 minute or less contact with the gastrointestinal environment.

Based on the history of safe use of these materials as shown in the firm's compliance assessment, the expert report from Dr. Bill Bradbury and the Cytotoxicity testing (MEM Elution) report, there are no new concerns impacting safety / effectiveness regarding biocompatibility and omission of Sensitization and Irritation tests is justified.

Therefore, the proposed device is substantially equivalent to the predicates in this regard.

IX. Software

N/A - No software

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Item	Present & Acceptable?	Location in Submission
Electrical Safety	**N/A**	**N/A**
Electromagnetic Compatibility	**N/A**	**N/A**
Mechanical	**YES**	**Included as part of performance testing - device operated as intended**

Consensus Standards
The manufacturer identified the following consensus standards as being used in the design and testing of the device:

STANDARD	DESCRIPTION
AAMI / ANSI / ISO 10993-7:1995	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. [Recognition No. 14-76]
EN 980:1996 + A1:1999 + A2:2001	Graphical Symbols for Use in the Labeling of Medical Devices. [Recognition No. 5-32]
ANSI / AAMI / ISO 10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing. [Recognition No. 2-98]
AAMI / ANSI / ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 1ed. [Recognition No. 14-294]
AAMI / ANSI / ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. [Recognition No. 14-228]
ISO 14971:2007	Medical devices - Application of risk management to medical devices. [Recognition No. 5-40]

XI. Performance Testing – Bench

The firm provided Performance / Animal Testing in **Section III, Page 26** of the original submission. It is a comparative study between the proposed ERBELIFT™ system and the predicate Needle Injection System (K924102) for submucosal elevation (lift) in ex-vivo and in-vivo porcine models. A summary of this testing is provided below:

Purpose:
To determine whether a hand-pump needle-free elevation system will affect procedure time and generate tissue elevation without complication when compared to a needle system.

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SD1.4.1q (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Test Method:

A) Ex-Vivo Study

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRHREGSTATUS@fda.hhs.gov or call 301-796-8118.

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Product: ERBELIFT™ Hand Pump and Flexible Probe

(b) (4)

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XVII. Recommendation

Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscopic Injector Needle, Gastroenterology / Injector, Fluid, Non-Electrically Powered
Regulatory Class:	II
Product Code:	FBK

Primary Third Party Reviewer:

Bhavesh Shah 09 JUL 2009

for Daniel W. Lehtonen — Date
Sr. Staff Engineer - Medical Devices

Responsible Third Party Official:

Jay Y. Kogoma — Date
Sr. Staff Engineer - Medical Devices

Branch Chief — Date

The following Appendices are attached to this review memo

SE Flowchart ..... Appendix A1.1
Written Communications in Reverse Chronological Order ..... Appendix A1.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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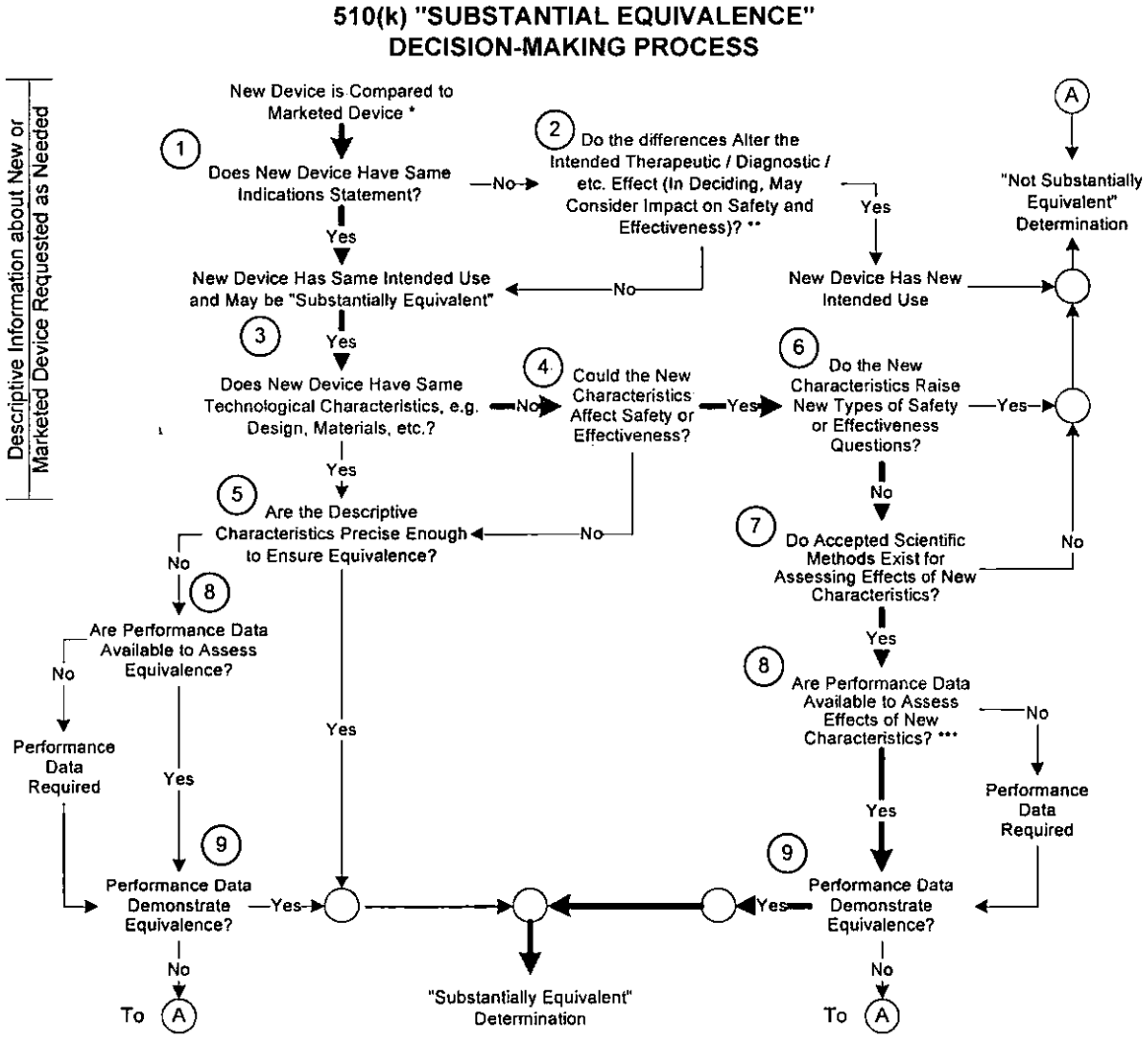
Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Appendix A1.1

SE Flowchart



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post Amendments) device is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Product: ERBELIFT™ Hand Pump and Flexible Probe

Appendix A1.2

Written Communications in Reverse Chronological Order

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Dan Lehtonen Intertek

From: Erica Matthes [erica.matthes@erbe-usa.com]
Sent: Thursday, July 09, 2009 6:25 PM
To: Dan Lehtonen Intertek
Cc: John Tartal; Chris Hierholzer
Subject: RE: 3179301 Byrne ERBELift

Dan –

I hope it is ok, but I actually just rewrote the entire statement you proposed. Mine maybe a bit wordy, I just want to drive the point home and clarify.

In the in-vivo study one of the endpoints was "perforation at maximum force". In our conversation, this was defined as the maximum pull / activation force applied to the trigger of the hand pump by the user who is also deliberately ignoring the visual tissue effect – essentially simulating negligent use of the product.

The purpose of this endpoint within the in-vivo study was simulate if a perforation (worst case failure mode) of the tissue could occur when the device is not operated per the intended use - :i.e. if an untrained user, activates the trigger of the hand pump in a negligent manner (quick, strong pull force) in a thin walled tissue area, which does not require a high pull force to achieve a submucosal lift under direct visualization.

The results were such that no perforations were caused.

Please let me know if you have any questions.
Regards,
Erica Matthes

From: Dan Lehtonen Intertek [mailto:dan.lehtonen@intertek.com]
Sent: Thursday, July 09, 2009 5:15 PM
To: John Tartal; Erica Matthes
Cc: Chris Hierholzer
Subject: 3179301 Byrne ERBELift

Hello John / Erica -

Please confirm the following is accurate based on our phone conversation from this afternoon.

In the in-vivo study one of the endpoints was "perforation at maximum force". In our conversation, this was defined as the maximum force applied to the hand pump from the user and that the purpose of this endpoint of the study was to use the device in a manner that was outside what would considered acceptable use - which is a series of quick strong pulls of the handle to determine if a perforation would occur.

The results were such that no perforations were caused.

Please reply confirming this or changing as necessary.

If there are any questions please let me know.

Thanks,

Dan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Fax: 330-405-5518
E-mail: dan.lehtonen@intertek.com

www.intertek-etlsemko.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Tuesday, July 07, 2009 4:01 PM
To: Dan Lehtonen Intertek
Cc: Chris Hierholzer; Erica Matthes
Subject: RE: 3179301 - ERBELift 510k Update
Attachments: 510(k) Summary Revised 07-07-09.doc; ERBE ERBEJET 2 510(k) K072404 Biocompatibility Study Applicators, PEEK Pages.pdf

Dear Dan,

Hopefully an E-mail response to both questions s acceptable.

1. Attached is the revised 510(k) Summary. Sorry for the error.

2. PEEK was unfortunately not put on the table by mistake in the ERBEJET 510(k) K072404. However, it is apart of the ERBEJET 2 Applicators/Probe and was included in the biocompatibility study in the 510(k). See attached selected pages of the study in 510(k) "PEEK" circled. So Dr. Bradbury's statement is correct (Note: Tissue contact is potential much longer with ERBEJET Applicators/Probe in that the saline is used to cut/dissect tissue.).

Sincerely,
John Tartal
QA/RA Manager
ERBE USA, Inc.

From: Dan Lehtonen Intertek [mailto:dan.lehtonen@intertek.com]
Sent: Tuesday, July 07, 2009 2:56 PM
To: chierholzer@byrnemedical.com
Cc: John Tartal
Subject: 3179301 - ERBELift 510k Update

Hi Chris / John,

We have completed the review of the responses provided on 01 Jul 2009 and have following questions:

1) The regulation number cited in the revised 510(k) summary (Section III, Page 1) is 87**5**.1500, which needs to be change to 87**6**.1500. Please provide an updated summary. E-copy is acceptable.

2) On page 2 of the Biocompatibility Risk Assessment Report (generated by Dr. Bill Bradbury), "the catheter shaft of the proposed ERBELIFT Flexible Probe is made of Victrex PEEK and this same material is used for catheter shaft of the previously cleared ERBEJET Flexible Probe (K072404)." However, in reviewing the 510(k) summary for K072404 (as provided on the FDA website), the materials used for ERBEJET Flexible Probe are identified as Plastics (ABS, PA, PVC), Stainless Steel, Silicone, Rubber and Synthetic Jewel (Corundum). Please clarify the use of PEEK in the previously cleared ERBEJET (K072404).

Please let me know if there are any questions.

Thanks,

Dan

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7/9/2009 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Dan Lehtonen Intertek
Sent: Tuesday, July 07, 2009 2:56 PM
To: 'chierholzer@byrnemedical.com'
Cc: 'john.tartal@erbe-usa.com'
Subject: 3179301 - ERBELift 510k Update

Hi Chris / John,

We have completed the review of the responses provided on 01 Jul 2009 and have following questions:

1) The regulation number cited in the revised 510(k) summary (Section III, Page 1) is 875.1500, which needs to be change to 876.1500. Please provide an updated summary. E-copy is acceptable.

2) On page 2 of the Biocompatibility Risk Assessment Report (generated by Dr. Bill Bradbury), "the catheter shaft of the proposed ERBELIFT Flexible Probe is made of Victrex PEEK and this same material is used for catheter shaft of the previously cleared ERBEJET Flexible Probe (K072404)." However, in reviewing the 510(k) summary for K072404 (as provided on the FDA website), the materials used for ERBEJET Flexible Probe are identified as Plastics (ABS, PA, PVC), Stainless Steel, Silicone, Rubber and Synthetic Jewel (Corundum). Please clarify the use of PEEK in the previously cleared ERBEJET (K072404).

Please let me know if there are any questions.

Thanks,

Dan

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Thursday, June 25, 2009 7:05 PM
To: Dan Lehtonen Intertek
Cc: Erica Matthes
Subject: RE: Conference Call
Attachments: Comparison Table.doc; Biocompatibility Risk Assessment.pdf; Sterilization and Cytotoxicity (MEM Elution) Test Reports.pdf

Dear

Thank you for your time. Our discussion was very helpful. Attached is the Comparison Table in word as requested. I also include the Biocompatibility Risk Assessment as well as Sterilization and Cytotoxicity (MEM Elution) Test Reports (Note: The Assessment and Reports will be included in our response to the deficient report).

Sincerely,
John Tartal
QA/RA Manager
ERBE USA, Inc.

From: Dan Lehtonen Intertek [mailto:dan.lehtonen@intertek.com]
Sent: Thursday, June 25, 2009 5:10 PM
To: John Tartal
Subject: Conference Call

Hi John,

I can be available most anytime on Friday in the AM. The afternoon looks busy already, but I might be able to switch some things around if that fits your schedule. Just let me know a convenient time and I can confirm availability.

Thanks,

Dan

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Nicole Bartolozzi Intertek
Sent: Wednesday, June 24, 2009 4:27 PM
To: chierholzer@byrnemedical.com
Cc: Dan Lehtonen Intertek; Bhavesh Sheth Intertek; john.tartal@erbe-usa.com
Subject: 510k - Byrne Medical 3179301 - Deficiency Report I
Attachments: 3179301__Def Rpt.doc

Mr. Hierholzer,

Attached please find Intertek's deficiency report, which serves to provide a complete list of deficiencies found in the 510(k) premarket submission. A written response (three hard copies and one electronic) is required for the deficiencies identified.

After you have had an opportunity to review the findings, and determine an approximate date that we should expect your response, please contact me via phone at (330) 405-3552 or e-mail at nicole.bartolozzi@intertek.com so that your responses may be scheduled for review.

If after reviewing the content of this report there are questions, please contact your reviewer, Dan Lehtonen via e-mail at dan.lehtonen@intertek.com, phone at (937) 313-7454, or fax at (330) 405-5518.

Best Regards,
Nicole

Nicole Bartolozzi

510(k) Administrative Assistant
Phone: 330-405-3552

Intertek
2307 East Aurora Road, Suite B7

Twinsburg, Ohio 44087, USA

fax: 330-405-5518

E-mail: Nicole.Bartolozzi@intertek.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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www.intertek-etlsemko.com

19 Jun 2009

Mr. Chris Hierholzer
Byrne Medical, Inc.
3150 Pollok Drive
Conroe, TX 77303

SUBJECT: Deficiency Report
Device Name ERBELIFT™ Hand Pump and Flexible Probe
Intertek Project No. 3179301

Dear Mr. Hierholzer,

Following are the deficiencies found in the 510(k) premarket submission for the ERBELIFT™ Hand Pump and Flexible Probe.

Please cut and paste the table beginning on the following page into a document that you create on your letterhead and insert your responses to the deficiencies in the identified area of the table. Using this format will simplify the review of the information that you provide.

This is the final report and serves to provide a complete list of deficiencies found in the 510(k) premarket submission. A written response is required for the deficiencies identified.

After you have had an opportunity to review the findings, and determine an approximate date that we should expect your response, please contact Nicole Bartolozzi via phone at (330) 405-3552 or e-mail at nicole.bartolozzi@intertek.com so that your responses may be scheduled for review.

If after reviewing the content of this report there are questions, please contact me via e-mail at dan.lehtonen@intertek.com, phone at (937) 313-7454, or fax at (330) 405-5518.

Please reference the project number when replying.

Yours sincerely,

Daniel W. Lehtonen

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices

CC: Nicole Bartolozzi, 510(k) Administrative Assistant
John Tartal, ERBE

This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
1.	**Location:**	**Missing – Standards Data Report for 510(k)s**
	Finding:	In Section I, Page 6 of your submission you make reference to standards EN 980 and ISO 11607-2. The FDA requires that Form 3654 be included with all 510(k) submissions that reference a national or international standard. A separate form is required for each standard referenced in the 510(k). Please complete the identified form for EN 980 and ISO 11607-2. The form is available on the FDA website at the following link: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf Note: Please reference the amendments (A1:1999 and A2:2001) in the standard title for EN 980.
	Response:	
2.	**Location:**	**Missing – Summary Reports**
	Finding:	In Section III, Pages 13-15, you have provided FDA Form 3654 for ISO 10993-1, ISO 11135-1 and ISO 10993-7. Per these forms, summary reports are stated to be provided. However, no such reports could be located in the submission. Please provide summary reports for the above mentioned standards to demonstrate the extent of conformance of these standards.
	Response:	
3.	**Location:**	**Section III, Page 4 – 510(k) Summary (Conclusions)**
	Finding:	You have stated that the technological characteristics of the proposed ERBELIFT system are 'similar' as compared to the predicates. However, in reviewing the submission the technological characteristics of the proposed needle less system are significantly different as compared to the predicates with needle system. Please update this section to state the technological characteristics as 'different' and provide a revised 510(k) summary.
	Response:	

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
4.	**Location:**	**Section III, Page 17 – Declaration of Conformance with Consensus Standards**
	Finding:	You have not listed the consensus standards ISO 14971, EN 980, ISO 11607-2 and ISO 10993-7 in the 'Declaration of Conformance'. However, these standards have been identified in the Utilization of Standards page of the CDRH Cover Sheet (Section I, Page 6). Please provide a revised 'Declaration of Conformance with Consensus Standards' identifying all applicable standards or include rationale as to how the standards are used.
	Response:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
5.	**Location:**	**Section III, Page 19 – Biocompatibility Testing**
	Finding:	You have provided a summary of biocompatibility for individual materials of the proposed device. For biocompatibility assessment, FDA recommends that the test articles be extracted from the finished, sterilized device. Also, there may be possible contamination while assembling the device. Please explain as to how the data provided demonstrates the biocompatibility of the finished sterilized device. Alternatively, please provide a revised biocompatibility testing for the final finished device. Per, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the following tests are recommended for the proposed device: Cytotoxicity, Sensitization and Irritation (or Intracutaneous Reactivity). The compliance assessment and the basis provided for individual materials are not adequate to justify the omission of Sensitization and Irritation tests. Please provide a detailed explanation as to how the omission of these tests will not affect the biocompatibility of the finished device. Alternatively, please provide biocompatibility reports for Sensitization and Irritation tests. Please reference the standard* as applicable for specific tests and ensure that all the test reports follow the extent of regulation of respective standard. Also, please include a separate form 3654 for additional standards (if any) that are referenced in the submission. *Per the FDA website, ISO 10993-10 is the recommended biocompatibility standard for irritation and delayed-type hypersensitivity tests. Also, per extent of regulation for ISO 10993-1, ccompliance with FDA Good Laboratory Practices (GLPs) regulation is required. Please revise the biocompatibility section to indicate that the testing is done in accordance with GLP guidelines. Additionally, there are references to the cytotoxicity and biocompatibility risk assessment reports in the submission; however no such reports could be located. Please provide these reports, since they are necessary for assessing biocompatibility. Note: Please revise the Utilization of standards list in the CDRH Coversheet and the Declaration of Conformity to reflect the identification of additional standards.
	Response:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
6.	**Location:**	**Section III, Page 20 – Materials Used**
	Finding:	Per FDA Guidance Document for the Traditional 510(k) dated August 12, 2005, it is recommended that adequate material information be provided for all the device components that come into direct or indirect contact with the patient. Please provide material designation and manufacturer information for the following materials: Nylon 11 (Clear) and Nylon 11 (White). Also, please clarify the model number of Polyetheretherketone (PEEK) and provide material specifications sheet for the Colorcon MD-1185 and Colorcon MD-1210. Additionally, please identify the K number of the control syringe intended to be used as an accessory with the proposed device.
	Response:	
7.	**Location:**	**Missing – Contraindications (Instructions for Use Manual: Proposed Labeling)**
	Finding:	Per labeling provided on Page 4, the use of the predicate K924102 is contraindicated for uncooperative patients and/or patients with severe coagulopathy. Also, as stated on Page 23, the contraindication for the predicate K040961 include those specific to any endoscopic procedure, uncooperative patients, and patients with coagulopathy. In reviewing the Instructions for Use Manual for the proposed device, there are no contraindications provided. Please provide revised labeling with the contraindications included or provide a rationale explaining why you feel the contraindications are not applicable to your device.
	Response:	
8.	**Location:**	**Section V, Pages 32 – Safety Precautions / Warnings**
	Finding:	The predicate labeling provided for comparison contains precautions / warnings specific to endoscopic procedures and handling of the device. However, the proposed labeling does not include these warnings / precautions. Since, the proposed device employs a comparable endoscopic procedure (except for needle injection), please revise the labeling to include relevant warnings / precautions.
	Response:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
9.	**Location:**	**Section V, Pages: 34 & 35 – Marketing Statements / Claims**
	Finding:	The marketing statements / claims for the proposed device state: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe, especially with wet gloves. The information provided in the submission does not support any of the above mentioned claims. Please remove these claims or provide scientific explanation to substantiate them. Please note that claims of this nature typically require clinical data for substantiation. If such data is needed, the device will not be eligible for 3rd Party Review and will need to be withdrawn and submitted directly to FDA. Also, on Page 35, you claim that "in larger working channel scopes, the Probe may be able to be passed down alongside another instrument." Please provide a scientific discussion and supporting information as to how the integrity of the probe will remain unaffected with the presence of another instrument within the working channel. Alternatively, please remove this claim and revise the section.
	Response:	
10.	**Location:**	Throughout Submission - Classification Identification
	Finding:	The classification for the device is identified as 876.1500 (FBK) and / or 880.5430 (KZE). Please revise all documents (e.g. CDRH cover sheet, summary, etc.) to identify the classification as the 876.1500 (FBK) or revise to include both classifications and a detailed discussion supporting the classification designation.
	Response:	
END		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Dan Lehtonen Intertek

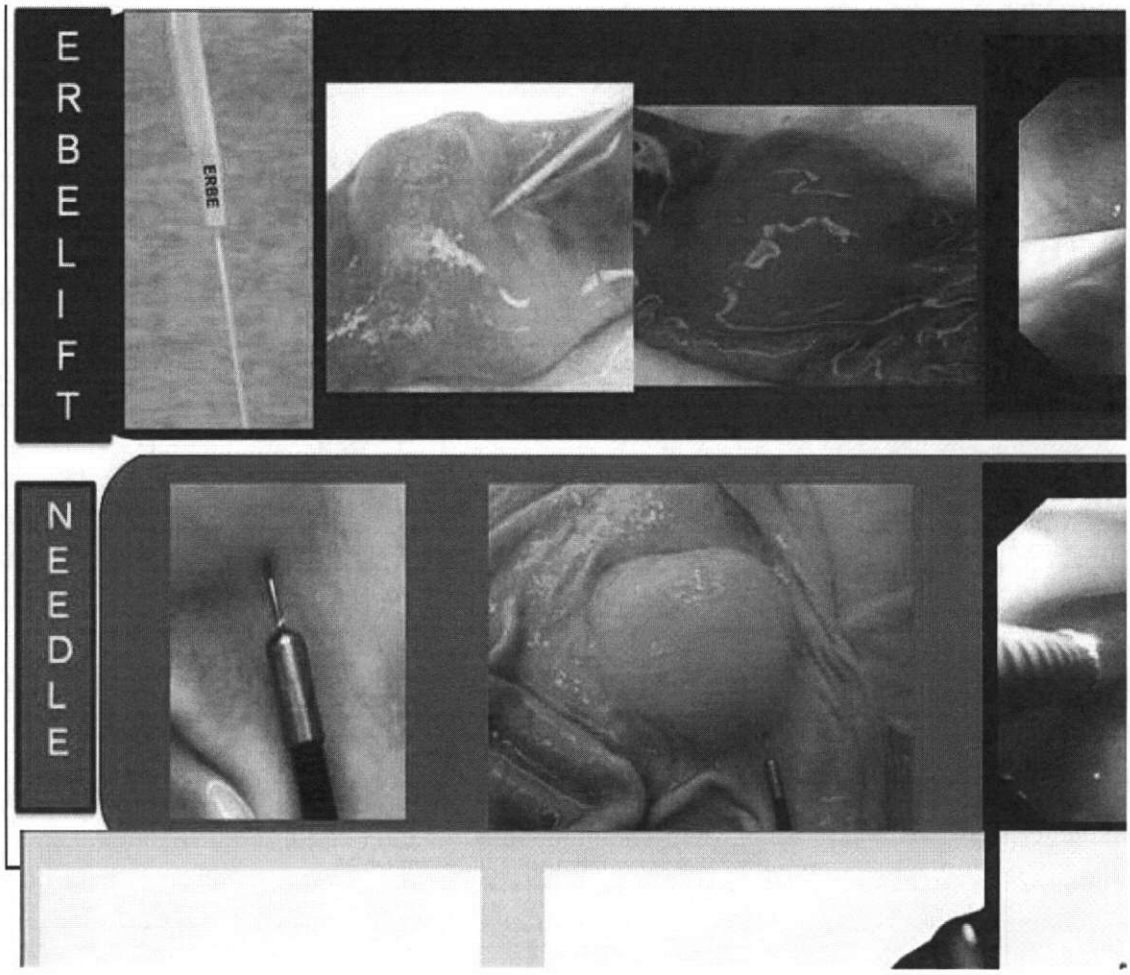
From: Erica Matthes [erica.matthes@erbe-usa.com]
Sent: Wednesday, June 10, 2009 12:09 AM
To: Dan Lehtonen Intertek
Cc: Erica Matthes; John Tartal
Subject: ERBELIFT 510(k) - Images you requested
Attachments: image002.jpg

Dear Dan –

It was a pleasure speaking with you today, and I appreciate all the questions. Please let John and I know if you have any other questions, so we can assist you in seeing this submission successfully to the FDA. I am available at any time, please see my contact information at the bottom of this email, for questions as mentioned in our call today.

Per your request, please see the images from the Performance Testing in color below. I also added a schematic of the submucosal elevation below to assist in your understanding of the procedure. I apologize for not emailing it sooner, but I was bogged down in meetings (as you well know) until the end of the day today. Hopefully this will help with your summary / follow up to our call, which John and I look forward to reviewing.

Let me know if I can be of any other further assistance.
Regards,
Erica



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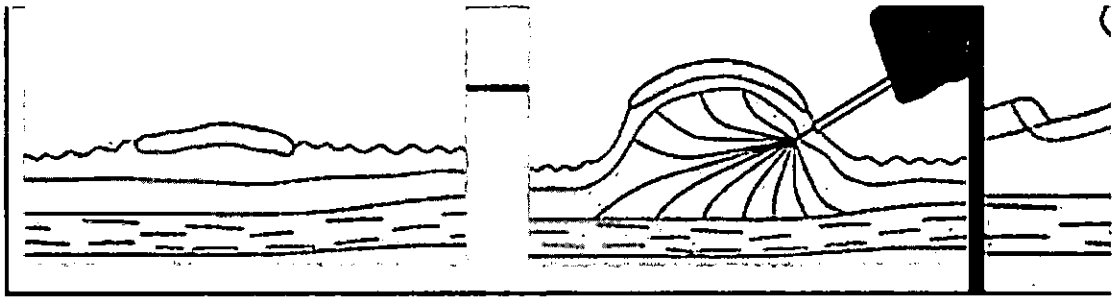

****
Erica L. Matthes
Technical Product Manager
ERBE USA Inc.
2225 Northwest Parkway
Marietta, GA 30067-9317
Tel: (770) 955-4400 or (800) 778-3723 ext. 123
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Web: www.erbe-usa.com
****

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

K Number _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) Do Sections 1 and 2

☐ Abbreviated 510(k) Do Sections 1, 3 and 4

☒ Traditional 510(k) (Or no identification provided) Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

Item	Present or Adequate	Missing or Inadequate	Location in Submission
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	X		Section 1 page 1
Table of Contents.	X		Front page
Truthful and Accurate Statement.	X		Section 2 Page 1
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X		Section 1 Page 4
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	X		Section 1 Page 4
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	X		Section 5 Page 29-35
Statement of Indications for Use that is on a separate page in the premarket submission.	X		Separate Page
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	X		Section 3 Page 5-10
510(k) Summary or 510(k) Statement.	X		Section 3 Page 1-4
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	X		Section 4
Identification of legally marketed predicate device. *	X		Section 1 Page 4
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA		
Class III Certification and Summary. **	NA		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA		
510(k) Kit Certification ***	NA		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Section 2: Required Elements for a SPECIAL 510(k) submission:

Item	Present or Adequate	Missing or Inadequate	Location in Submission
Name and 510(k) number of the submitter's own, unmodified predicate device.			
A description of the modified device and a comparison to the sponsor's predicate device.			
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.			
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.			
A Design Control Activities Summary that includes the following elements (a-c):			
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.			
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.			
c. A Declaration of Conformity with design controls that includes the following statements:			
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.			
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.			

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

Item	Present or Adequate	Missing or Inadequate	Location in Submission
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)			
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]			
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.			
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.			
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.			
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.			

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

Item	Present or Adequate	Missing or Inadequate	Location in Submission
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	X		Section 3 Page 18-26
b) Sterilization and expiration dating information:	X		Section 3 Page 31
i) sterilization process	X		
ii) validation method of sterilization process	X		
iii) SAL	X		
iv) packaging	X		
v) specify pyrogen free	NA		
vi) ETO residues	X		
vii) radiation dose	NA		
viii) Traditional Method or Non-Traditional Method	Traditional		
c) Software Documentation		NA	

Passed Screening: X **Yes** ____ **No**

Reviewer: Daniel W. Lehtonen for Joseph Shetn **Date:** 06 May 2009

Concurrence by Review Branch: _____

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-EGISTATUS@fda.hhs.gov or call 301-796-8118.

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Contents of Supplement Tab Dated 07 Jul 2009

Additional / Replacement Information Provided by the Sponsor in Support of Their 510(k) Submission

Each item is separated by a light blue sheet of paper

1. Overall Response Letter From Firm for Request for Information
2. Final version: 510(k) Summary
3. Response to verify the use of PEEK (Polyetheretherketone) in a previously cleared device - ERBEJET (K072404)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Tuesday, July 07, 2009 4:01 PM
To: Dan Lehtonen Intertek
Cc: Chris Hierholzer; Erica Matthes
Subject: RE: 3179301 - ERBELift 510k Update
Attachments: 510(k) Summary Revised 07-07-09.doc; ERBE ERBEJET 2 510(k) K072404 Biocompatibility Study Applicators, PEEK Pages.pdf

Dear Dan,

Hopefully an E-mail response to both questions s acceptable.

1. Attached is the revised 510(k) Summary. Sorry for the error.

2. PEEK was unfortunately not put on the table by mistake in the ERBEJET 510(k) K072404. However, it is apart of the ERBEJET 2 Applicators/Probe and was included in the biocompatibility study in the 510(k). See attached selected pages of the study in 510(k) "PEEK" circled. So Dr. Bradbury's statement is correct (Note: Tissue contact is potential much longer with ERBEJET Applicators/Probe in that the saline is used to cut/dissect tissue.).

Sincerely,
John Tartal
QA/RA Manager
ERBE USA, Inc.

From: Dan Lehtonen Intertek [mailto:dan.lehtonen@intertek.com]
Sent: Tuesday, July 07, 2009 2:56 PM
To: chierholzer@byrnemedical.com
Cc: John Tartal
Subject: 3179301 - ERBELift 510k Update

Hi Chris / John,

We have completed the review of the responses provided on 01 Jul 2009 and have following questions:

1) The regulation number cited in the revised 510(k) summary (Section III, Page 1) is 87<u>5</u>.1500, which needs to be change to 87<u>6</u>.1500. Please provide an updated summary. E-copy is acceptable.

2) On page 2 of the Biocompatibility Risk Assessment Report (generated by Dr. Bill Bradbury), "the catheter shaft of the proposed ERBELIFT Flexible Probe is made of Victrex PEEK and this same material is used for catheter shaft of the previously cleared ERBEJET Flexible Probe (K072404)." However, in reviewing the 510(k) summary for K072404 (as provided on the FDA website), the materials used for ERBEJET Flexible Probe are identified as Plastics (ABS, PA, PVC), Stainless Steel, Silicone, Rubber and Synthetic Jewel (Corundum). Please clarify the use of PEEK in the previously cleared ERBEJET (K072404).

Please let me know if there are any questions.

Thanks,

Dan

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 2

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510(k) SUMMARY

Submitted By:	Byrne Medical Incorporated 3150 Pollock Drive Conroe, TX 77303 Tel: 936-539-0391 Fax: 936-539-2381
Contact Person:	Chris Hierholzer Quality Control Manager
Date Prepared:	April 22, 2009
Common Name:	Injector
Trade/Proprietary Name:	ERBELIFT™ Hand Pump and Flexible Probe
Classification Name:	Endoscopic Injection Needle (21 CFR Part 876.1500)
Product Code:	FBK
Legally Marketed Predicate Device:	Endoscopic Injection Needle 510(k) Number: K924102 and Endoscopic Injection Needle/Snare 510(k) Number: K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has slightly different principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 221

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 3

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Materials Used

Applicators

Material	Body Contact
(b) (4)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Summary of Examined Materials

(b) (4)

No.	Material	Page

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

BIOCOMPATIBILITY STUDY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Contents of Supplement Tab Dated 01 Jul 2009

Additional / Replacement Information Provided by the Sponsor in Support of Their 510(k) Submission

Each item is separated by a light blue sheet of paper

1. Overall Response Letter From Firm for Request for Information
2. Revised: CDRH Coversheet (Page 5) – Utilization of Standards
3. Revised: 510(k) Summary
4. Biocompatibility – Risk Assessment report, Sterilization Report, MEM Elution (Cytotoxicity) report
5. Material Specification Sheets: PEEK, Nylon 11, Titanium dioxide, GeneSolv S-T, Colorcon MD-1185 & Colorcon MD-1210
6. Revised: Instructions for Use Manual
7. Revised Documents: Classification identification – 876.1500 (FBK)
   CDRH Coversheet (Page 3), FDA Form 3674 and Submission Summary (Section I, Page 11)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Byrne Medical, Inc.
The Universal Irrigation Solution

3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

June 29, 2009

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087
Attn: Daniel W. Lehtonem,
Senior Staff Engineer – Medical Devices

Intertek Project No.: 3179301 – ERBELIFT™ Hand Pump and Flexible Probe

Additional information was requested regarding the above project through your Deficiency Report dated 06/19/09 and E-Mailed on 06/24/09. To facilitate your review, the questions with our responses are included in the table that was provided with changes as well as additions as part of Exhibits. We have included one complete paper copy and one electronic copy. Please accept this material into the record for the Project/510(k).

We believe that the response enclosed has adequately resolved the request as noted. However, if you have any further questions or need technical assistance, please call John Tartal at (770) 955-4400 or email direct at "John.Tartal@erbe-usa.com".

Sincerely,

Chris Hierholzer
Quality Control Manager
Byrne Medical, Inc.

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Item		Description of Deficiency
1.	**Location:**	**Missing – Standards Data Report for 510(k)s**
	Finding:	In Section I, Page 6 of your submission you make reference to standards EN 980 and ISO 11607-2. The FDA requires that Form 3654 be included with all 510(k) submissions that reference a national or international standard. A separate form is required for each standard referenced in the 510(k). Please complete the identified form for EN 980 and ISO 11607-2. The form is available on the FDA website at the following link: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf Note: Please reference the amendments (A1:1999 and A2:2001) in the standard title for EN 980.
	Response:	Form 3654 for ISO 14971, EN 980, 11607-02 (That is Standards in Section I, Page 6 in which Forms 3654 were not completed) were not submitted in the 510(k) for the Standards because the Form for these Standards cannot be accurately completed (Note: There is no test data, etc. involved with these standards.). These standards provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively. I have spoken with FDA regarding this matter and was told to use the Form and Summary Report for Standards in applicable situations. As requested amendments (A1:1999 and A2:2001) were included in the standard title for EN 980 on Section I, Page 6. See Exhibit 1.
2.	**Location:**	**Missing – Summary Reports**
	Finding:	In Section III, Pages 13-15, you have provided FDA Form 3654 for ISO 10993-1, ISO 11135-1, and ISO 10993-7. Per these forms, summary reports are stated to be provided. However, no such reports could be located in the submission. Please provide summary reports for the above mentioned standards to demonstrate the extent of conformance of these standards.
	Response:	A Summary Report was completed as Declaration of Conformance with Consensus Standards for each of the above Standards. See Page III-16 for ISO 10993-1. ISO 11135-1 and ISO 10993-7 are Standards that involve sterilization guidelines (i.e., EO validation and EO residuals). The Declaration of Conformance with Consensus Standards for ISO 11135-1 and ISO 10993-7 Standards were provided on Page III-17. Also, the involved Sterility Information regarding these Standards is provided on Page III-31. In the past, providing the Summary Reports in this manner was acceptable to FDA.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Item		Description of Deficiency
3.	**Location:**	**Section III, Page 4 – 510(k) Summary (Conclusions)**
	Finding:	You have stated that the technological characteristics of the proposed ERBELIFT system are 'similar' as compared to the predicates. However, in reviewing the submission the technological characteristics of the proposed needle less system are significantly different as compared to the predicates with needle system. Please update this section to state the technological characteristics as 'different' and provide a revised 510(k) summary.
	Response:	The conclusion was revised. See Exhibit 2. Note: The entire 510(k) Summary was provided in the Exhibit without the "Confidential" identifier so that it could be used for FDA's posting of the 510(k).
4.	**Location:**	**Section III, Page 17 – Declaration of Conformance with Consensus Standards**
	Finding:	You have not listed the consensus standards ISO 14971, EN 980, ISO 11607-2 and ISO 10993-7 in the 'Declaration of Conformance'. However, these standards have been identified in the Utilization of Standards page of the CDRH Cover Sheet (Section I, Page 6). Please provide a revised 'Declaration of Conformance with Consensus Standards' identifying all applicable standards or include rationale as to how the standards are used.
	Response:	ISO 10993-7 was included as a Declaration of Conformance with Consensus Standards on Page III-17. Again, ISO 14971, EN 980, ISO 11607-2 are Standards that provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively; therefore, Declaration of Conformance with Consensus Standards for these Standards is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Item		Description of Deficiency
5.	**Location:**	**Section III, Page 19 – Biocompatibility Testing**
	Finding:	You have provided a summary of biocompatibility for individual materials of the proposed device. For biocompatibility assessment, FDA recommends that the test articles be extracted from the finished, sterilized device. Also, there may be possible contamination while assembling the device. Please explain as to how the data provided demonstrates the biocompatibility of the finished sterilized device. Alternatively, please provide a revised biocompatibility testing for the final finished device. Per, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the following tests are recommended for the proposed device: Cytotoxicity, Sensitization and Irritation (or Intracutaneous Reactivity). The compliance assessment and the basis provided for individual materials are not adequate to justify the omission of Sensitization and Irritation tests. Please provide a detailed explanation as to how the omission of these tests will not affect the biocompatibility of the finished device. Alternatively, please provide biocompatibility reports for Sensitization and Irritation tests. Please reference the standard* as applicable for specific tests and ensure that all the test reports follow the extent of regulation of respective standard. Also, please include a separate form 3654 for additional standards (if any) that are referenced in the submission. *Per the FDA website, ISO 10993-10 is the recommended biocompatibility standard for irritation and delayed-type hypersensitivity tests. Also, per extent of regulation for ISO 10993-1, ccompliance with FDA Good Laboratory Practices (GLPs) regulation is required. Please revise the biocompatibility section to indicate that the testing is done in accordance with GLP guidelines. Additionally, there are references to the cytotoxicity and biocompatibility risk assessment reports in the submission; however no such reports could be located. Please provide these reports, since they are necessary for assessing biocompatibility. Note: Please revise the Utilization of standards list in the CDRH Coversheet and the Declaration of Conformity to reflect the identification of additional standards.
	Response:	The materials for the Flexible Probe were chosen based upon their long history of biocompatibility as well as their use in medical applications (e.g., many disposable medical instruments, catheters, shunts, etc. use these materials.). Our initial assessment of the need to only perform Cytotoxicity was confirmed by a Biocompatibility Risk Assessment generated by an independent expert (Dr. Bill Bradbury). See Exhibit 3.1. Prototype samples (Note: The entire Flexible Probe) were prepared by our contract manufacturer using the same manufacturing processes that will be employed for the finished medical device. These samples were sent to a contract testing laboratory. The Flexible Probes were sterilized (sterilization representing greater than 2X) and then the Cytotoxicity (MEM Elution) testing was performed. Reactivity was "0" (Note: Sterilization and Testing was done under GLP.). See Exhibit 3.2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Item		Description of Deficiency
6.	**Location:**	**Section III, Page 20 – Materials Used**
	Finding:	Per FDA Guidance Document for the Traditional 510(k) dated August 12, 2005, it is recommended that adequate material information be provided for all the device components that come into direct or indirect contact with the patient. Please provide material designation and manufacturer information for the following materials: Nylon 11 (Clear) and Nylon 11 (White). Also, please clarify the model number of Polyetheretherketone (PEEK) and provide material specifications sheet for the Colorcon MD-1185 and Colorcon MD-1210. Additionally, please identify the K number of the control syringe intended to be used as an accessory with the proposed device.
	Response:	As provided in the biocompatibility study (See Page III-20) , PEEK, Nylon 11 White, Genesolv S-T (Solvent), and Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer) are the materials that have the potential of indirect and/or direct patient contact (Note: Not Nylon Clear). The requested additional material information is as follows: PEEK: Victrex® *PEEK* Type 381G, Natural [Material Safety Data Sheet (MSDS) CAS#31694-16-3 – 381G] {See Exhibit 4.1} Nylon 11 White: Elf Atochem North America Nylon 11 (Clear) [MSDS CAS# - 25587-80-8 - Part # 0096 – Medron] with Whittaker, Clarke, and Daniel Inc. 0.9 wt.% Titanium Dioxide (TiO_2) [MSDS CAS # 13463-67-7] {See Exhibit 4.2} Genesolv ST (Solvent): Honeywell Genesolv S-T [MSDS] {See Exhibit 4.3} Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer): Colorcon Black Ink (MD-1185) & Colorcon Reducer (MD-1210) [MSDSs] {See Exhibit 4.4} ***Note: For additional information in regards to materials of the device and as well as indirect and direct patient exposure reference Page IV-5 (Device Drawing), Pages III-18 to III-26 (Biocompatibility Study) and Exhibit 3.1 (Biocompatibility Risk Assessment by Independent Expert Dr. Bill Bradbury)*** Control Syringe: Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings); 510(k) Number K920135

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Item		Description of Deficiency
7.	**Location:**	**Missing – Contraindications (Instructions for Use Manual: Proposed Labeling)**
	Finding:	Per labeling provided on Page 4, the use of the predicate K924102 is contraindicated for uncooperative patients and/or patients with severe coagulopathy. Also, as stated on Page 23, the contraindication for the predicate K040961 include those specific to any endoscopic procedure, uncooperative patients, and patients with coagulopathy. In reviewing the Instructions for Use Manual for the proposed device, there are no contraindications provided. Please provide revised labeling with the contraindications included or provide a rationale explaining why you feel the contraindications are not applicable to your device.
	Response:	The statement, "Contraindications: The use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy.", was added to the labeling (Instructions For Use). See Exhibit 5.
8.	**Location:**	**Section V, Pages 32 – Safety Precautions / Warnings**
	Finding:	The predicate labeling provided for comparison contains precautions / warnings specific to endoscopic procedures and handling of the device. However, the proposed labeling does not include these warnings / precautions. Since, the proposed device employs a comparable endoscopic procedure (except for needle injection), please revise the labeling to include relevant warnings / precautions.
	Response:	I have meticulously reviewed the "Warnings and Precautions" in the labeling of the predicates for statements which are applicable in our labeling. I find that I have included all necessary statements as "Safety Instructions- Warnings" as follows: Training, not using damaged product, not using product in which there may be a package integrity issue, not using product beyond its expiration, etc. (Note: All of these statements were considered as a result of our risk assessment.). Many statements in the "Warnings and Precautions" for the predicate devices actually do not belong in the section (e.g., the device being single use, compatibility of working channel scope size, solution types, etc.). The information is instructional in nature and diminishes the effectiveness of the "real" Warnings and Precautions in the predicate labeling. Therefore, as directed by FDA, some of the statements in the predicate labeling Warnings and Precautions section are included in our labeling but not in our "Safety Instructions- Warnings" section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Item		Description of Deficiency
9.	**Location:**	**Section V, Pages: 34 & 35 – Marketing Statements / Claims**
	Finding:	The marketing statements / claims for the proposed device state: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe, especially with wet gloves. The information provided in the submission does not support any of the above mentioned claims. Please remove these claims or provide scientific explanation to substantiate them. Please note that claims of this nature typically require clinical data for substantiation. If such data is needed, the device will not be eligible for 3rd Party Review and will need to be withdrawn and submitted directly to FDA. Also, on Page 35, you claim that "in larger working channel scopes, the Probe may be able to be passed down alongside another instrument." Please provide a scientific discussion and supporting information as to how the integrity of the probe will remain unaffected with the presence of another instrument within the working channel. Alternatively, please remove this claim and revise the section.
	Response:	Substantiation of Claim: "***An easier and less demanding method of generating force to drive the fluid into the submucosa.***" Pulling the trigger of the ERBELIFT Hand Pump ergonomically designed pistol grip hand pump allows for less activation force to push the plunger of the syringe compared to an in-line motion like when the user uses their hand force applied to syringe connected to an injection needle. Substantiation of Claim: "***Flexible Probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe,.***" The winged luer lock on the ERBELIFT Flexible Probe provides more surface area for the user's fingers to grasp onto when twisting the luer to lock or unlock – this additional winged surface area is not available on standard leur locks used on the injection needles. Note: "***especially with wet gloves***" was removed from the statement. See Exhibit 6. **"In larger working channel scopes, the Probe may be able to be passed down alongside another instrument."** was removed from the list. See Exhibit 6.

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Item		Description of Deficiency
10.	**Location:**	Throughout Submission - Classification Identification
	Finding:	The classification for the device is identified as 876.1500 (FBK) and / or 880.5430 (KZE). Please revise all documents (e.g. CDRH cover sheet, summary, etc.) to identify the classification as the 876.1500 (FBK) or revise to include both classifications and a detailed discussion supporting the classification designation.
	Response:	All documents in the submission were changed to identify the device's classification as only 876.1500 (FBK). See Exhibit 7 (Also Exhibit 2).

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 2

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Exhibit 1

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical devices - Application of risk management to medical devices	N/A	2007
2	10993-1	AAMI ANSI ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing	N/A	2003
3	EN 980	EN	Graphical Symbols for Use in the Labelling of Medical Devices (A1:1999 and A2:2001)	N/A	2003
4	11607-2	AAMI ANSI ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	N/A	2006
5	11135-1	AAMI ANSI ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	N/A	2007
6	10993-7	AAMI ANSI ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	N/A	1995
7					

Please include any additional standards to be cited on a separate page.

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 3

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Exhibit 2

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510(k) SUMMARY

Submitted By:	Byrne Medical Incorporated 3150 Pollock Drive Conroe, TX 77303 Tel: 936-539-0391 Fax: 936-539-2381
Contact Person:	Chris Hierholzer Quality Control Manager
Date Prepared:	April 22, 2009
Common Name:	Injector
Trade/Proprietary Name:	ERBELIFT™ Hand Pump and Flexible Probe
Classification Name:	Endoscopic Injection Needle (21 CFR Part 875.1500)
Product Code:	FBK
Legally Marketed Predicate Device:	Endoscopic Injection Needle 510(k) Number: K924102 and Endoscopic Injection Needle/Snare 510(k) Number: K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

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The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

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Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has slightly different principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 4

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Exhibit 3.1

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Biocompatibility Risk Assessment

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ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067-9317
Attn: Erica L Matthes

March 24, 2009

SUBJECT:

Biocompatibility Risk Assessment related to the ERBELIFT™ Flexible Probe, Part Number (REF): 7912-1002.

PURPOSE AND SCOPE:

The purpose of this Risk Assessment is to support that the ERBELIFT™ Flexible Probe is not a biocompatibility risk based upon the fundamental principles outlined in FDA G95-1 Memorandum and the ISO10993, Part 1 Standard.

(b) (4)

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3.0 Luer Hub: Nylon 11, White

3.1 The Hub, molded to the Proximal end of the 260 cm shaft will only have indirect contact with the Gastrointestinal mucosal and compromised tissue through contact with the normal saline that passes through the Probe and is force-injected into the tissue.

MATERIAL CHARACTERIZATION / RISK ASSESSMENT:

(b) (4)

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(b) (4)

SUMMARY:

The above information supports the biocompatibility and safe patient use for the ERBELIFT™ Flexible Probe. A minimum or no-risk of adverse biocompatibility is indicated from the 5 minute or less contact with the Gastrointestinal environment. No adverse biocompatibility effects are expected at the brief point of contact of the Probe tip or from the injected saline.

In conclusion, biocompatibility per the fundamental principles outlined in FDA G95-1 Memorandum and the ISO10993, Part 1 Standard has been confirmed and no further biocompatibility testing was considered necessary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 280

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REFERENCES:

1. The ERBEJET Flexible Probe covered by FDA 510k Number: K072404, October 31, 2007.
   http://www.erbe-usa.com/products/ERBEJET2.asp

2. Colorcon NO-TOX Medical Device Ink (MDI)
   Http://www.colorcon.com/notox/home

3. Genesolv ST used in "delicate medical applications, eg. plastic catheter line cleaning".
   http://www.epa.gov/ozone/snap/solvents/EPASolventMarketReport.pdf

SIGNATURE: DATE: March 24, 2009

William C. Bradbury, PhD
Bradbury Consulting Service Inc.
16860 Tamarind Rd
Sugarloaf, FL 33042-3515
305 745-2822
drbillbrad@aol.com

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Exhibit 3.2

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Testing Reports

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sterilization

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Viewing Data For: My Data

Study Details for Lab Number: 463420

Final Report (2 MB - please right-click and save this file)

Study Information:

Sample ID:	ENG-022009 2 units
Test Description:	SEC210: Sterilization Exposure Cycles: Steris Cycle, 100% EO (up to 5 hours chamber time)
PO Number:	
Study Director:	Phil Tuckett
Study Type:	GLP
Turn Around:	Standard
Alerts:	

Study Dates:

Samples Received:	20 Feb 2009
Test Started:	25 Feb 2009
Test Finished:	27 Feb 2009
QA Received (GLP):	02 Mar 2009
QA Reviewed (GLP):	02 Mar 2009
Report Mailed:	02 Mar 2009

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FINAL REPORT

(b) (4)

PROCEDURE NO. (b) (4)
PROTOCOL DETAIL SHEET NO. (b) (4)

LABORATORY NO (b) (4)

PREPARED FOR:

JOHN TARTAL
ERBE-USA, INC.
2225 NORTHWEST PARKWAY
MARIETTA GA 30067

SUBMITTED BY:

(b) (4)

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(b)(4) Lab Test Results

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(b)(4) Lab Test Results

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(b)(4) Lab Test Results

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(b)(4) Lab Test Results

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Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 5

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Exhibit 4.1

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(b)(4) Contracting data

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MATERIAL SAFETY DATA SHEET

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Exhibit 4.3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Material Safety Data Sheet

(b) (4)

Medtronic Pat# 04d1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

MATERIAL SAFETY DATA SHEET

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

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(b) (4)

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MATERIAL SAFETY DATA SHEET

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Exhibit 4.4

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(b)(4) Contractor Results

Material Safety Data Sheet

(b)(4) Contractor Results

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(b)(4) Contractor Results

Material Safety Data Sheet

(b)(4) Contractor Results

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 6

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Exhibit 5

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

ERBELIFT™ *Instruction For Use*
Hand Pump and Flexible Probe

Caution! Federal law restricts this device to sale by or on the order of a physician.

Hand Pump, No. 7912-1001
Reusable Pump that is loaded with a sterile normal saline-filled syringe which connects to a Flexible Probe (Note: The Hand Pump can be used for 100 procedures).

Flexible Probe, No. 7912-1002
Single use Probe that connects to a sterile normal saline-filled syringe that is loaded into a Hand Pump.

Accessories Needed but Not Provided
Normal Sterile Saline
Syringe Type: DeRoyal Medical Products, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings) Control Syringe, Product Number 77-712391. An 8 ml size can also be used (Product Number 77-400391).

Note: The working channel of the endoscope must have a diameter larger than 1.5 mm.

Safety Instructions

WARNINGS

The products may only be used by medical personnel who have been trained per these instructions.

Hand Pump
Clean/Disinfect the Hand Pump prior to using the device the first time and before every subsequent use. Before each use, check that the product is intact. Verify that there are no signs of physical damage. If damaged, do not use this product. Protect this product from any form of mechanical damage.

Flexible Probe
Sterility is not guaranteed if the package has been opened or damaged. Discard if the package is damaged. An expiration date is printed on the packaging of the device. Do not use any product beyond its expiration date. When using the device clinically (within a patient), do not puncture the mucosa with the Probe's tip. Dispose of the product after use. The device is only intended to be used once. Do not re-sterilize.

Byrne Medical, Inc. expressly warns against modifying the products. Any modification exempts Byrne Medical, Inc. from any and all liability.

Contraindications: The use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy.

Intended use

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

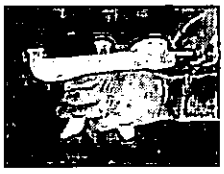
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 314

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

How to use

1. Prior to use, clean and disinfect the Hand Pump by using a hospital grade disinfectant. Follow the manufacturer's instructions for using the disinfectant.

2. Pull back the plunger of the Hand Pump.



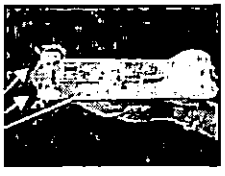
3. Using accepted medical methods, open the packaging of the syringe and fill it with sterile normal saline.

4. Use aseptic techniques to open the pouch of the Flexible Probe and remove the Probe from its protective sheath (i.e. hoop).

Note: Ensure that the Probe's integrity is not compromised throughout its use.

5. Connect the Probe's hub luer to the syringe. Ensure that the connection is secure.

6. Load the syringe into the barrel of the Hand Pump at the three (3) connection points.



Connection Points

7. Using accepted medical methods, squeeze the trigger of the Hand Pump to purge the attached Flexible Probe of air with the normal saline (i.e. purge the Probe.).

8. When needed, place the distal end of the Flexible Probe down the working channel of the endoscope. Under direct visualization, place the Probe's tip against the target tissue where a submucosal lift is desired (Note: Do not puncture the mucosa with the Probe's tip.).

9. To create the desired lift, squeeze the handle in a controlled manner while viewing the cushion formation. Create other lifts as desired.

10. After use, remove the Flexible Probe from the endoscope. The Probe may be a potential biohazard. Therefore, handle and dispose of the Probe in accordance with accepted medical practices as well as with local, state and federal regulations. Finally, disinfect the Hand Pump by using a hospital grade disinfectant. Follow the manufacturer's instructions for using the disinfectant.

ERBE
USA INCORPORATED
Surgical Systems

Distributor:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Phone No.: 770-955-4400 or 800-778-3723
Fax No.: 770-955-2577

Manufacturer: Byrne Medical, Inc.; 3150 Pollok Drive; Conroe, TX 77303

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Exhibit 6

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ERBELIFT™ Hand Pump and Flexible Probe Marketing Statements/Claims

- The ERBELIFT Hand Pump and Flexible Probe produces submucosal elevations as traditional needle-injection systems.
- Easy to use devices.
- An easier and less demanding method of generating force to drive the fluid into the submucosa.
- Needle-less submucosal elevation.
- No mechanical trauma of using a needle, need to find the submucosal plane with a needle, or perforation with a needle.
- Hand Pump
  - Ergonomic Pistol Grip Design:
    - Supports natural wrist posture / position.
    - Intuitive hand placement.
    - Ambidextrous operation.
    - Form and dimensions to accommodate both the female or male user's anthropometric hand specifications.
    - Center of gravity passes through the grip of the handle of the grasping hand, minimizing fatigue.
    - Curved handle design to avoid compressive forces against the soft tissue of the hand[1].
    - Non-slip materials support the effective grip between the wet, gloved hands and the pump.
  - Comfortable, One Hand Activation:
    - Easy operation due to less gripping force compared to an in-line tool handle or motion (e.g. force applied to syringe connected to an injection needle)[2].
    - The separation length of the trigger to the handle base allows either a male for female user to wrap up to four fingers around the trigger and maximize their grip pull strength[3].
    - The length and shape of the trigger allows either a male for female user to comfortably wrap up to four fingers around the trigger to minimize discomfort during multiple activations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 317

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

ERBELIFT™ Hand Pump and Flexible Probe
Marketing Statements/Claims

- The user can easily control when to immediately stop and / or to reinitiate the flow due to the mechanical drive mechanism per pull / activation.

- Easy to monitor fluid volume from the mounted control syringe since each activation (trigger pull) delivers a quantified output.

- Flexible Probe
  - Connecting hub with standard luer lock that is winged which allows easy connection to the syringe.
  - Small outer diameter tubing which is compatibility with a large range of flexible endoscope working channel sizes.
  - Smooth but sturdy tubing allows for easy insertion in a scope as well as removal from a scope.
  - There is no needle to cause damage to the channel of the scope.

[1] http://www.advancedergonomics.com/product/tools.htm

[2] http://www.agrabilityproject.org/assistivetech/tips/handtools.cfm

[3] http://www.ccohs.ca/oshanswers/ergonomics/handtools/tooldesign.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item 7

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Exhibit 7

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K924102	1	Injection Needle	1	United States Endoscopy Group, Inc.
2	K040961	2	Injection Needle/Snare	2	United States Endoscopy Group, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Injector

	Trade or Proprietary or Model Name for This Device		Model Number
1	ERBELIFT™ Hand Pump and Flexible Probe	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FBK

C.F.R. Section *(if applicable)*: 876.1500

Classification Panel: Gastroenterology/Urology and/or General Hospital

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616. Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR//APPLICANT//SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Byrne Medical, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   Jun 29, 2009

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   3150 Pollock Drive
   Conroe, TX 77303

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 936-539-0391
   (Fax) 936-539-2381

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Injector, Code FBK (No.: 876.1500)

   ERBELIFT™ Hand Pump and Flexible Probe

APPLICATION//SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT//INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*
   - ☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
   - ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
   - ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Chris Hierholzer
    (Title) QC Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    3150 Pollock Drive
    Conroe, TX 77303

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 936-539-0391
    (Fax) 936-539-2381

15. DATE OF CERTIFICATION
    Jun 29, 2009

PSC Graphics (301) 443-1090 EF

Form FDA 3674 (11/08) (FRONT)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

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   Injector, Code FBK (No.: 876.1500)

   ERBELIFT™ Hand Pump and Flexible Probe

APPLICATION / SUBMISSION INFORMATION

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CERTIFICATION STATEMENT / INFORMATION

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    (Title) QC Manager

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    (Tel.) 936-539-0391
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15. DATE OF CERTIFICATION
    Jun 29, 2009

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed In number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

SUBMISSION SUMMARY

(A) 510(k) Premarket Notification

(1)	Trade (Proprietary) Name:	ERBELIFT™ Hand Pump and Flexible Probe
(2)	Common Name:	Injector
(3)	Classification Name:	Endoscopic Injection Needle
(4)	Establishment Number:	1651395
	Owner/Operator:	Byrne Medical Incorporated 3150 Pollock Drive Conroe, TX 77303
(5)	Class:	II
	Regulation:	21 CFRs 876.1500
	Panel:	Gastroenterology-Urology and/or General Hospital
	Product Code:	FBK

(B) Compliance with Performance Standards

The ERBELIFT™ Hand Pump and Flexible Probe were tested as applicable using "Recognized Consensus Standards". See Section III, Product Data - Declaration of Conformance with Consensus Standards.

(C) Proposed Labeling

Refer to Section V, Device Labels and Labeling as well as Marketing Statements for the proposed labeling of the ERBELIFT Hand Pump and Flexible Probe. There are draft package labels and labeling (i.e. Instructions For Use) in this Section.

The predicate product labeling is also in Section V.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Indications for Use

510(k) Number (if known): _____

Device Name: Byrne Medical, Inc.'s ERBELIFT™ Hand Pump and Flexible Probe

Indications For Use:

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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This document and any print made there from are proprietary property of Byrne Medical Incorporated and protected under title 5, section 552, US Code. Unauthorized disclosure is prohibited.

The information and design disclosed herein was originated by and is the property of Byrne Medical Incorporated. Byrne Medical Incorporated reserves all patent, proprietary, design, manufacturing, reproduction, use and sale rights thereto, and to any article disclosed therein, except to the extent rights are expressly granted in writing to others.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Byrne Medical, Inc.
The Universal Irrigation Solution

3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

April 22, 2009

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

RE: Traditional 510(k): Byrne Medical, Inc. - ERBELIFT™ Hand Pump and Flexible Probe

Dear Intertek Reviewer,

Per agreement, three (3) original paper copies of the submission with one (1) having all original signatures are enclosed with an electronic copy.

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR Part 807, premarket notification is hereby made of the intention of Byrne Medical, Inc. to introduce into interstate commerce for commercial distribution ERBELIFT Hand Pump and Flexible Probe. This notification authorizes Intertek to submit this 510(k) to FDA as well as discuss the submission with the Agency.

See the CDRH Submission Cover Sheet for the 510(k)'s general elements and the Table of Contents for specific locations of the information in support of the elements. It was Byrne Medical's attention to have included all the necessary information to support the review. However if any more information is needed or questions arise, please feel free to contact the technical support person for the submission, Mr. John Tartal at 1-800-778-3723 Ext. 133.

Thank you in advance for your timely review.

Sincerely,

Chris Hierholzer
Quality Control Manager
Byrne Medical, Inc.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
4/22/2009		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Byrne Medical, Inc.	Establishment Registration Number *(if known)* (b) (4)		
Division Name *(if applicable)*	Phone Number *(including area code)* (936) 539-0391		
Street Address 3150 Pollok Drive	FAX Number *(including area code)* (936) 539-2381		
City Conroe	State / Province TX	ZIP/Postal Code 77303	Country USA
Contact Name Chris Hierholzer			
Contact Title Quality Control Manager	Contact E-mail Address chierholzer@byrnemedical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K924102	1	Injection Needle	1	United States Endoscopy Group, Inc.
2	K040961	2	Injection Needle/Snare	2	United States Endoscopy Group, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Injector

	Trade or Proprietary or Model Name for This Device		Model Number
1	ERBELIFT™ Hand Pump and Flexible Probe	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
FBK and/or KZE

C.F.R. Section *(if applicable)*
876.1500 and/or 880.5430

Device Class
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Classification Panel
Gastroenterology/Urology and/or General Hospital

Indications *(from labeling)*

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9041235	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Byrne Medical, Inc.		Establishment Registration Number (b) (4)		
Division Name *(if applicable)* N/A		Phone Number *(including area code)* (936) 539-0391		
Street Address 3150 Pollok Drive		FAX Number *(including area code)* (936) 539-2381		
City Conroe		State / Province TX	ZIP/Postal Code 77303	Country USA
Contact Name Chris Hierholzer	Contact Title Quality Control Manager		Contact E-mail Address chierholzer@byrnemedical.com	

(b) (4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical devices - Application of risk management to medical devices	N/A	2007
2	10993-1	AAMI ANSI ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing	N/A	2003
3	EN 980	CEN	Graphical Symbols for Use in the Labelling of Medical Devices	N/A	2003
4	11607-2	AAMI ANSI ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	N/A	2006
5	11135-1	AAMI ANSI ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	N/A	2007
6	10993-7	AAMI ANSI ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	N/A	1995
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Byrne Medical, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Apr 22, 2009

3. ADDRESS *(Number, Street, State, and ZIP Code)*
3150 Pollok Drive
Conroe, TX 77303

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 936-539-0391
(Fax) 936-539-2381

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Injector, Code FBK (No.: 876.1500) and/or Code KZE (No.: 880.5430)

ERBELIFT™ Hand Pump and Flexible Probe

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Chris Hierholzer
(Title) QC Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
3150 Pollok Drive
Conroe, TX 77303

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 936-539-0391
(Fax) 936-539-2381

15. DATE OF CERTIFICATION
Apr 22, 2009

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Form FDA 3674 (11/08) (BACK)

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510(k) ELEMENTS LIST

510(k) Elements	Authority (21 CFR)	Location in the 510(k)
Statement of Indications for Use that is on a separate page in 510(k) submission	807.92(a5)	Separate Page
Table of Contents	807.87	X
510(k) Cover Letter	807.87	I-1
CDRH Premarket Review Submission Cover Sheet	FDA Form 3514	I-2 to I-7
Submitter's name and address	807.87	I-2, I-11, III-1
Contact person, telephone number and fax number	807.87	I-1, I-2, III-1
Representative/Consultant if applicable	807.87	I-2, III-1
Truthful and Accurate Statement	807.87(k)	II-1
Device Trade Name, Device's Classification Name	807.87	I-4, I-11, III-1
Establishment registration number (only applies if establishment is registered)	807.87	I-2, I-5, I-11
Device Classification Regulation Number and Regulatory Status (Class I, II, or III or Unclassified)	807.87	I-4, I-11
Name and address of manufacturing/packaging/ sterilization facilities. Establishment registration number of each facility when one exists	807.87	I-5
Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1)	807.87	V-29 to V-35
Identification of the marketed device(s) to which equivalence is claimed including labeling and description of the device	807.87	I-4, I-14, III-1, V-1 to V-28
Statement of similarities and/or differences with marketed device(s)	807.87	I-13 to I-14, III-2 to III-3
Comparison table of the new device to the marketed device(s) or modified device (whichever applicable)	807.87	III-5 to III-10
510(k) summary or a 510(k) statement	807.87(h) 807.92	I-11 to I-15, III-1 to III-3

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510(k) Elements	Authority (21 CFR)	Location in the 510(k)
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals	807.87	IV-1 to IV-5
Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards & FDA-3654 completed for international standards	807.87(d)	III-13 to III-15
For class III only, a class III certification and a class III summary.	807.87(i)	N/A
Certification of Compliance with Requirements of clinical Trials	FDA From 3674	I-8
Biocompatibility data for all patient-contacting materials, or certification of identical material / formulation	807.87	III-13, III-15, III-18 to III-26
Sterilization information (Blue Book Memo #K90-1)	807.87	III-31
Software information (Blue Book Memo #K91-1)	807.87	N/A
Performance Testing	807.87	III-27 to III-30
Hardware information	807.87	IV-1 to IV-5
Information requested in specific guidance documents (if applicable for this device)	807.87	I-1 to V-35
Kit Certification Statement (for kit submission only)	807.87	N/A

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SUBMISSION SUMMARY

(A) 510(k) Premarket Notification

(1)	Trade (Proprietary) Name:	ERBELIFT™ Hand Pump and Flexible Probe
(2)	Common Name:	Injector
(3)	Classification Name:	Endoscopic Injection Needle
(4)	Establishment Number:	1651395
	Owner/Operator:	Byrne Medical Incorporated 3150 Pollok Drive Conroe, TX 77303
(5)	Class:	II
	Regulation:	21 CFRs 876.1500 an/or 880.5430
	Panel:	Gastroenterology-Urology and/or General Hospital
	Product Code:	FBK and/or KZE

(B) Compliance with Performance Standards

The ERBELIFT™ Hand Pump and Flexible Probe were tested as applicable using "Recognized Consensus Standards". See Section III, Product Data - Declaration of Conformance with Consensus Standards.

(C) Proposed Labeling

Refer to Section V, Device Labels and Labeling as well as Marketing Statements for the proposed labeling of the ERBELIFT Hand Pump and Flexible Probe. There are draft package labels and labeling (i.e. Instructions For Use) in this Section.

The predicate product labeling is also in Section V.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 339

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(D) Device Description

1. **General Description**

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 340

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2. **Similarities and Differences to the Predicate Devices.**

a. **Similarities**

The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

b. **Differences**

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 341

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The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

The ERBELIFT Hand Pump and Flexible Probe has been verified or validated in design control. The proposed device is substantially equivalent to the predicate devices documented in the following 510(k) submissions:

Applicant	Predicate Device	510(k) Number
United States Endoscopy Group, Inc.	Injection Needle	K924102
United States Endoscopy Group, Inc.	Injection Needle/Snare	K040961

The comparison table of the predicate devices and the ERBELIFT™ Hand Pump and Flexible Probe can be found in Section III, Product Data - Comparison Table.

c. **Indications for Use**

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 342

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3. **Cleaning/Disinfection and Sterilization Information**
The ERBELIFT Hand Pump will be sold non-sterile, reusable. Cleaning/Disinfection directions for the Pump are in the Instructions For Use. See Section V, Proposed Labeling. The Flexible Probe will be sold sterile, single use and is sterilized using ethylene oxide. See Section III, Product Data - Sterility Information.

4. **Design Controls**
Byrne Medical, Inc. in accordance with established procedures directs and controls design activities. These procedures involve design and development planning, design input, design review, design verification/design output, design validation, design transfer, as well as design change control. The activities provide the oversight and forum for project approval, formal management/design review, evaluation, and final project approval. This work is documented within design review and the approvals are documented as part of the current change control system. See Section III, Product Data - Declaration of Conformity with Design Control Statements.

5. **Additional Information**
The "Truthful and Accurate Statement" is included in Section II. The "510(k) Summary" is included in Section III.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 343

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TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the President/CEO of Byrne Medical Inc., I believe to the best of my knowledge; that all data and information submitted in this premarket notification for the ERBELIFT™ Hand Pump and Flexible Probe are truthful and accurate and that no material fact has been omitted.

Don Byrne
President/CEO

4-23-09
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) SUMMARY

Submitted By:	Byrne Medical Incorporated 3150 Pollok Drive Conroe, TX 77303 Tel: 936-539-0391 Fax: 936-539-2381
Contact Person:	Chris Hierholzer Quality Control Manager
Date Prepared:	April 22, 2009
Common Name:	Injector
Trade/Proprietary Name:	ERBELIFT™ Hand Pump and Flexible Probe
Classification Name:	Endoscopic Injection Needle (21 CFR Part 875.1500) and/or Injector, Fluid, Non-Electrically Powered (21 CFR Part 880.5430)
Product Code:	FBK and/or KZE
Legally Marketed Predicate Device:	Endoscopic Injection Needle 510(k) Number: K924102 and Endoscopic Injection Needle/Snare 510(k) Number: K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.[1,2,3] Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue[4]. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has similar principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

[1] Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. Pediatr Ann. 1998;27:375–386.

[2] Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. Mil Med. 1963;128:516–524.

[3] Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254–261. (*http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm*

[4] Mitragotri S. Immunization without needles. Nat Rev Immunol. 2005;5:905–916

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8148.

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COMPARISON TABLE

Characteristics	**Predicate Devices**		**Proposed Device** (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Manufacturer and 510(k) Applicant	United States Endoscopy Group, Inc.	United States Endoscopy Group, Inc.	Byrne Medical, Inc.
510(k) Number	K924102	K040961	
Indications For Use *The Intended Use in Instructions For Uses are different.	Intended Use in 510(k)*: The U.S. Endoscopy needle is indicated for use with flexible gastoscopes, colonoscopes, sigmoidoscopes, duodenoscopes, choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of fluids or tissue and for injection of medications or dyes into tissue.	Intended Use in 510(k)*: The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.	The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

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Characteristics	**Predicate Devices**		**Proposed Device** (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Materials			
Hand Pump	Not Applicable	Not Applicable	Plastic and Stainless Steel
Needle or Probe	Plastics, Teflon, Metal, Stainless Steel	Plastics, Metal, Stainless Steel	Plastics and Medical Grade Inks with Reducer
Physical Characteristics			
Hand Pump	Not Applicable	Not Applicable	A Gun Shaped Device with a Handle and a Slot for Mounting a Syringe
Needle or Probe	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle and Snare	Handle with a Standard Luer Lock Connection Hub and Catheter (Tubing)
Dimensions			
Hand Pump	Not Applicable	Not Applicable	Barrel Length: 8-3/4" (22 cm) Width (Top of Barrel and Handle): 6" (15 cm) Thickness (Width of Barrel): 2-1/2" (6 cm)

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Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Needle or Probe	Working Length: 230 cm Working Outer Diameter (O.D.): 2.5 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm	Working Length: 230 cm Working Outer Diameter (O.D.): 3.0 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm Snare Maximum Extension Width: 2.5 cm	Working Length: 260 cm Working Outer Diameter: 1.3 mm Tip Inner Diameter/ Stream: 0.120 mm/ 120 µm
Force / Flow Rate	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	145 to 650 psi / 17 to 38 ml/minute
Labeling			
Hand Pump	Not Applicable	Not Applicable	Carton Label and Instructions For Use
Needle or Probe	Outer Packaging Labels and Instructions For Use	Outer Packaging Labels and Instructions For Use	Outer Packaging Pouch, Carton, and Case Labels as well as Instructions For Use
Condition Provided/ Use Condition			
Hand Pump	Not Applicable	Not Applicable	Non-sterile/ Reusable
Needle or Probe	Sterile/Disposable- Single Use	Same	Same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Sterilization Method Used by Manaufacturer			
Hand Pump	Not Applicable	Not Applicable	Not Sterilized
Needle or Probe	Ethylene Oxide	Same	Same
Cleaning/Disinfection			
Hand Pump	Not Applicable	Not Applicable	Method in Notes On Use
Needle or Probe	Not Applicable	Same	Same
Required Accessory	Syringe	Syringe	Syringe* *Designated Type
Delivered Medium/ Solutions	Medicinal Substances and Solutions as Follows: Sodium Morrhuate, Sodium Tetradecylsulfate, Ethynolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Medicinal Substances and Solutions as Follows: Sodium Morrhuate, Sodium Tetradecylsulfate, Ethynolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Sterile Normal Saline Note: Also, referred to as 0.9%NaCl or Physiological Saline. It is a specific concentration of "Hypertonic Saline".
Target Population	Endoscopic Patient Candidates with Polyps or Mucosal Lesions	Same	Same
Anatomical Site	Esophagus, Stomach, Duodenum, Small Intestine, and Large Intestine	Same	Same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Characteristics	**Predicate Devices**		**Proposed Device** (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
FDA Guidance Documents Used	Unknown	Unknown	Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s, 8/12/05
Performance Standards Met	Not Applicable	Same	Same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Other Standards Used or Applied/Met	Tripartite Biocompatibility Guidance for Medical Devices; AAMI Standards for Sterilization; Ethylene Oxide Residual Limits In Parts Per Million Based on Product Type and Size 43 FR 27482, June 23, 1978	Unknown	AAMI / ANSI / ISO 10993-1: 2003, Biological evaluation of medical devices, Part 1: Evaluation and testing; AAMI / ANSI / ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes; AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices; AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

SUMMARY OF DESIGN CONTROL ACTIVITIES

Byrne Medical, Inc.'s management, in accordance with established procedures, directs and controls design activities. These procedures involve design and development planning, design input, design review, design verification/design output, design validation, design transfer, as well as design change control. The activities provide the oversight and forum for project approval, formal management/design review, evaluation, and final project approval. This work is documented within the design review meeting minutes and the approvals are documented as a part of the current change control system.

The Risk Analysis method(s) used to assess the impact of the ERBELIFT™ Hand Pump and Flexible Probe followed ISO 14971: 2007 Medical devices - Application of risk management to medical devices.

A summary of the verification and validation activities with the respective standards used or applied/met is in the following Table.

Verification and Validation Activity Summary Table	
Verification/Validation Activity (Brief Description)	Standard Used or Applied/Met
Physical Characteristics in regards to Safety and Efficacy	Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s, 8/12/05
Biological Evaluation of Materials	AAMI / ANSI / ISO 10993-1
Labels and Labeling	21 CFR 801; EN 980
Packaging	AAMI / ANSI / ISO 11607-2
Sterilization	AAMI / ANSI / ISO 11135-1, AAMI / ANSI / ISO 10993-7

AAMI / ANSI / ISO 10993-1: 2003, Biological evaluation of medical devices, Part 1: Evaluation and testing

21 CFR 801, Labeling

EN 980: 2003, Graphical symbols for use in the labelling of medical devices

AAMI / ANSI / ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8018.

35C

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 10993-1: 2003 Biological evaluation of medical devices, Part 1: Evaluation and testing

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993-1: 2003, Biological evaluation of medical devices, Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Standard Data Report for 510(K)s; AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993-7: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-76	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DECLARATION OF CONFORMANCE WITH CONSENSUS STANDARDS

Standard[1]: AAMI / ANSI / ISO 10993-1: 2003: 2003 Biological evaluation of medical devices, Part 1: Evaluation and testing*

Requirement	Predicate Devices		ERBELIFT™ Flexible Probe
	Injection Needle	Injection Needle/Snare	
Medical Products in Contact to the Surface of the Body			
Cytotoxin Analysis [Duration of Contact is A - Short (≤ 24 hours)]			
Skin	Unknown	Unknown	Complies (Pass)
Mucosal Membranes	Unknown	Unknown	Complies (Pass)
Breached or Compromised Surfaces	Unknown	Unknown	Complies (Pass)
Sensitivity Testing [Duration of Contact is A - Short (≤ 24 hours)]			
Skin	Unknown	Unknown	Compliance Assessed
Mucosal Membranes	Unknown	Unknown	Compliance Assessed
Breached or Compromised Surfaces	Unknown	Unknown	Compliance Assessed
Irritation or Intracutaneous Reactivity [Duration of Contact is A - Short (≤ 24 hours)]			
Skin	Unknown	Unknown	Compliance Assessed
Mucosal Membranes	Unknown	Unknown	Compliance Assessed
Breached or Compromised Surfaces	Unknown	Unknown	Compliance Assessed
Medical Products which are Connected from the Outside with Tissues or Structures within the Body			
Cytotoxin Analysis [Duration of Contact is A - Short (≤ 24 hours)]			
Bloodstream path, Indirect	Not Applicable	Not Applicable	Not Applicable
Tissue / Bone / Dental Contact	Unknown	Unknown	Complies (Pass)
Circulating Blood	Not Applicable	Not Applicable	Not Applicable
Sensitivity Testing [Duration of Contact is A - Short (≤ 24 hours)]			
Bloodstream path, Indirect	Not Applicable	Not Applicable	Not Applicable
Tissue / Bone / Dental Contact	Unknown	Unknown	Compliance Assessed
Circulating Blood	Not Applicable	Not Applicable	Not Applicable
Irritation or Intracutaneous Reactivity [Duration of Contact is A - Short (≤ 24 hours)]			
Bloodstream path, Indirect	Not Applicable	Not Applicable	Not Applicable
Tissue / Bone / Dental Contact	Unknown	Unknown	Compliance Assessed
Circulating Blood	Not Applicable	Not Applicable	Not Applicable

*Also See Biocompatibility Study and Sterility Information

1 Each section contains multiple clauses and all clauses within a specific section, where applicable, passed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 360

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DECLARATION OF CONFORMANCE WITH CONSENSUS STANDARDS

Standard: AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Standard: AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

See Sterility Information regarding required information and all applicable specifications/acceptance criteria being met on III-31.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

BIOCOMPATIBILITY STUDY

Biological Evaluation of Medical Products based upon AMMI / ANSI / ISO 10993-1:2003(E)

Prepared By: Erica Matthes
Technical Product Manager
ERBE USA, Inc.

Date: 03/24/2009

Product Type: ERBELIFT™ Flexible Probe
Part Number (REF): 7912-1002

Manufacturer: Byrne Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 362

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Biocompatibility Testing Matrix

Medical Product Category			Biological Effect Basic Classification								Biological Effect Additional Classification				Validity for Product	
Body Contact		Duration of Contact A - Short (≤ 24 h) B - Long (> 24 h to 30 days) C - Permanent (> 30 days)	Cytotoxin Analysis	Sensitivity Testing	Irritation or Intracutaneous Reactivity	Systemic Toxicity (Acute)	Subchronic Toxicity (Subacute Toxicity)	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproduction/Development	Biodegeneration	Yes	No
Surface Devices	Skin	A	X	X	X										X	
		B	X	X	X											X
		C	X	X	X											X
	Mucosal Membranes	A	X	X	X										X	
		B	X	X	X											X
		C	X	X	X		X	X								X
	Breached or Com-promised Surfaces	A	X	X	X										X	
		B	X	X	X											X
		C	X	X	X		X	X								X
External Communi-cating Devices	Bloodstream path, Indirect	A	X	X	X	X				X						X
		B	X	X	X	X				X						X
		C	X	X		X	X	X		X	X	X				X
	Tissue / Bone / Dental Contact	A	X	X	X										X	
		B	X	X				X	X							X
		C	X	X				X	X			X				X
	Circulating Blood	A	X	X	X	X				X						X
		B	X	X	X	X		X		X						X
		C	X	X	X	X	X	X		X	X	X				X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 369

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

PERFORMANCE TESTING

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 372

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILITY INFORMATION

The ERBELIFT™ Flexible Probe is labeled as a sterile device. Pursuant to the 510(k) sterility review guidance for sterilized medical devices (February 12, 1990), the following information is provided.

1. Sterilization Methods Used:
   100% Ethylene Oxide Gas

2. Description of Sterilization Validation Cycle:
   The validation was designed per AAMI / ANSI / ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

3. Sterility Assurance Level:
   10^{-6}

4. Description of Packaging:
   Each ERBELIFT Flexible Probe is placed in a protective sheath (i.e. a plastic holder/hoop) and then packaged in a Tyvek Pouch. The pouch is suitable for ethylene oxide sterilization and designed for maintaining its integrity. Five (5) pouches are placed into a carton (Note: Cartons are then placed into as Case for sterilization and bulk finished device shipping). See Engineering Drawing of the Packaging in Section IV, Device Specific Technical Information, IV-6. AAMI / ANSI / ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes was followed to validate the packaging.

5. Ethylene Oxide Residuals:
   The ethylene oxide residual levels are being evaluated by following AAMI / ANSI / ISO 10993-1: 1995, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. Prior to the distribution of the ERBELIFT Flexible Probe, the following residual levels per the standard for each product will not exceed:

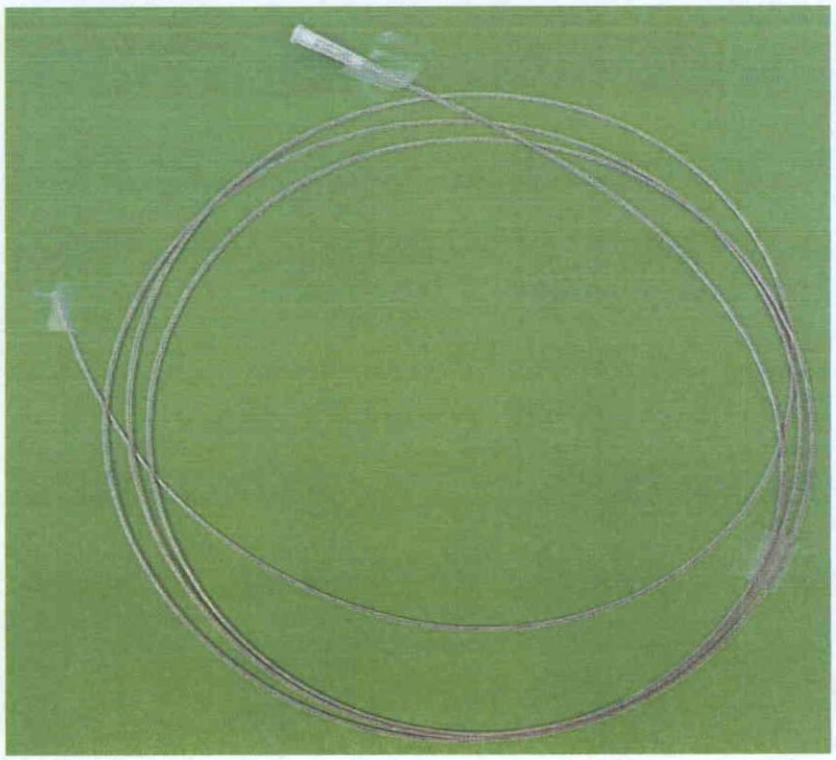
Ethylene Oxide (EO)	Ethylene Chlorohydrin (ECH)
20 mg in the first 24 hours	12 mg in the first 24 hours

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 375

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

PRODUCT PICTURES

ERBELIFT™ Hand Pump



ERBELIFT™ Flexible Probe

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DEVICE SPECIFICATIONS (ENGINEERING DRAWING)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

377

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PACKAGING SPECIFICATIONS (PACKAGING DRAWING)

(b) (4)

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PACKAGING SPECIFICATIONS (PACKAGING DRAWING)

(b) (4)

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CURRENT PREDICATE LABELING AND MARKETING MATERIAL

List of Current Predicate Labels and Labeling as well as Marketing Material

Description	Page Number
Injection Needle (Carr-Locke - injection needle)	
Label/Labeling (Instructions For Use)	
Outer Packaging Pouch Label	V-2
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Marketing Material	
Marketing Statements/Claims in Advertisements	V-17 to V-19
Injection Needle/Snare (iSnare™ - Injection therapy & polypectomy system)	
Labels/Labeling (Instructions For Use)	
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Instructions For Use	V-21 to V-26
Marketing Material	
Marketing Statements/Claims in Advertisements	V-27 to V-28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-3118.

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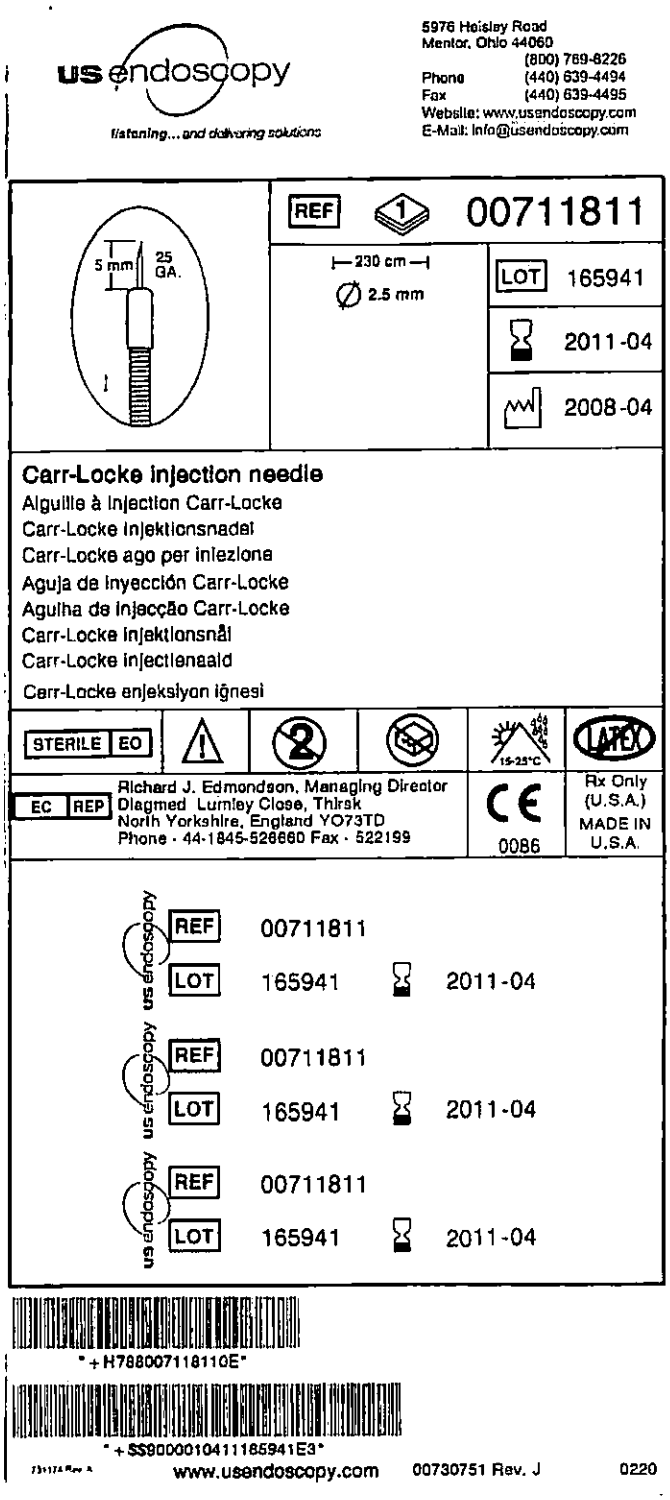

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REF 00711811

5 mm 25 GA.

230 cm
Ø 2.5 mm

LOT 165941
2011-04
2008-04

Carr-Locke injection needle
Aiguille à injection Carr-Locke
Carr-Locke injektionsnadel
Carr-Locke ago per iniezione
Aguja de inyección Carr-Locke
Agulha de injecção Carr-Locke
Carr-Locke injektionsnål
Carr-Locke injectienaald
Carr-Locke enjeksiyon iğnesi

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+SS9000010411185941E3

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Carr-Locke - injection needle Outer Packaging Pouch Label

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Articulator™ - injection needle

Articulator™ – Aiguille à injection	Reorder No. 00711803	(4mm / 160cm / 25ga)
Articulator™ – Injektionsnadel	Reorder No. 00711804	(5mm / 160cm / 25ga)
Articulator™ – ago per iniezione	Reorder No. 00711807	(5mm / 230cm / 25ga)
Articulator™ – Aguja de inyección	Reorder No. 00711808	(5mm / 350cm / 25ga)
Articulator™ – agulha de injecção		
Articulator™ – injektionsnål		
Articulator™ – injectienaald		
Articulator™ – enjeksiyon iğnesi		
Articulator™ – 주사기		

Carr-Locke - injection needle

Carr-Locke – Aiguille à injection	Reorder No. 00711811	(5mm / 230cm / 25ga)
Carr-Locke – Injektionsnadel	Reorder No. 00711813	(5mm / 230cm / 25ga)
Carr-Locke – ago per iniezione		
Carr-Locke – Aguja de inyección		
Carr-Locke – agulha de injecção		
Carr-Locke – injektionsnål		
Carr-Locke – injectienaald		
Carr-Locke – enjeksiyon iğnesi		
Carr-Locke – 주사기		

Vari-Safe™ - injection needle

Vari-Safe™ – Aiguille à injection	Reorder No. 00711818	(4mm / 230cm, 23ga)
Vari-Safe™ – Injektionsnadel	Reorder No. 00711819	(5mm / 230cm, 23ga)
Vari-Safe™ – ago per iniezione	Reorder No. 00711820	(7mm / 230cm, 23ga)
Vari-Safe™ – Aguja de inyección		
Vari-Safe™ – agulha de injecção		
Vari-Safe™ – injektionsnål		
Vari-Safe™ – injectienaald		
Vari-Safe™ – enjeksiyon iğnesi		
Vari-Safe™ – 주사기		

INSTRUCTIONS FOR USE
Instructions d'utilisation
Gebrauchsanweisung
Istruzioni per l'uso
Instrucciones de uso
Instruções de Utilização
Brugsanvisning
Gebruiksaanwijzing
Kullanım talimatları
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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STERILE EO Rx Only (U.S.A.)

Intended Use:
These single use, disposable, flexible sheath injection needles are intended to be used for the injection of various types of media through flexible endoscopes.

Warnings and Precautions:

- Flexible endoscopy procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, contraindications, complications and hazards prior to any endoscopic procedure. If reference information for endoscopic technique or contraindications is needed, call US Endoscopy.
- Do not use an injection needle if there is any apparent shipping or handling damage.
- These injection needles are compatible with endoscope channels of 2.8mm or larger.
- For Carr-Locke Injection needles only: Do not attempt to actuate the injection needle with the catheter in a straightened position. The injection needle has been engineered and manufactured with a specific "preload" that is necessary to assure a full projection and full retraction of the needle from the distal hub when the device is in very tortuous configurations. If the injection needle is actuated with the catheter in a straightened position, the "preload" may cause the needle's inner catheter to collapse and not allow for adequate injection. When handling the injection needle, always be aware of the distal tip of the needle, and visually confirm that the needle is fully retracted into the device.
- For Vari-Safe™ injection needles only: Do not attempt to activate or test the injection needle outside of the endoscope if the device is coiled more than once. It is possible that this may cause the injection needle to become lodged proximal to the distal tip spring.
- These injection needles are single use, disposable medical devices; they are not intended for reuse. Any institution, practitioner or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses these disposable devices must bear full responsibility for their safety and effectiveness.
- All of the injection needles included in this IFU (Instruction for Use) are compatible with the following medicinal substances and solutions: Sodium Morrhuate, Sodium Tetradecylsulfate, Ethynolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline and Staining Media.
- In addition, the Vari-Safe™ injection needles (product #s 00711818, 00711819, and 00711820) have been confirmed to be compatible with Triamcinolone (Kenalog). The compatibility of other substances has not been verified and therefore should not be attempted.
- The Carr-Locke and Articulator™injection needles (product numbers 00711811, 00711803, 00711804, 00711807, and 0071808) are not compatible with the Pentax Model 90 series High Definition gastroscopes, while the Carr-Locke injection needle (product number 00711813) is compatible with Pentax Model 90 series High Definition gastroscopes.

Contraindications: The use of this device is contraindicated for uncooperative patients and/or patients with severe coagulopathy.

Directions for Use:

1. (a) For Articulator™ & Carr-Locke Injection Needles Only: Carefully remove the tip protector from the distal tip of the needle. Actuate the proximal luer back and forth, visually observing the needle being adequately advanced from the device's distal end. The spring-loaded handle assists in needle retraction; however, always visually check the retraction as well. (Note: Product #00711808 version used for enteroscopy does not have this spring-loaded handle feature).
   (b) For Carr-Locke Injection Needle Usage in a Duodenoscope: When using this needle in a duodenoscope, before actuating the elevator to the full position, assure that the needle sheath is projected adequately past the end of the scope to prevent damage to the needle which, in the retracted position, is positioned inside the spring, proximal to the distal tip.
   (c) For Vari Safe™ injection needles only: The needle has been shipped in a "needle projected" position. This is necessary to keep the distal needle from catching on the distal spring. Carefully remove the tip protector from the distal tip of the needle. Uncoil the needle sheath and ensure that the needle is properly projected. Unlock the luer lock fitting and actuate the proximal luer back and forth, visually observing the needle being adequately advanced from the distal end. The return spring assists in the needle retraction; however, always visually check the retraction as well.
   Note: Do not stretch the device because stretching may cause the needle projection length to be altered.
2. To lock the needle in the out position, gently press the proximal luer until it meets the handle's luer, and then slowly twist the proximal luer clockwise until the two luers are fully engaged.
3. Using accepted medical methods, purge the needle assembly of air with the injection media.
4. Ensure that the needle is fully retracted prior to inserting it into the endoscope.
5. Proceed with injection of appropriate media using approved medical techniques until desired results are accomplished.
6. When moving from one injection site to the next, it is advisable to retract the needle into the sheath to protect the mucosa, as well as the endoscope, from trauma/damage.
7. When removing the injection needle from the endoscope, fully retract the needle into the sheath to protect the patient and clinician from injury, and to protect the endoscope from potential damage.

Product Disposal:
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: October 2008

Warning:
An issued or revision date for these instructions is included for the user's information. In the event two years has elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

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00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Application :
Les aiguilles à injection de gaine flexible jetables à usage unique sont destinées à l'injection de divers types de supports par le biais d'endoscopes flexibles.

Avertissements et précautions :

- Les procédures d'endoscopie flexible ne doivent être effectuées que par du personnel possédant la formation nécessaire et connaissant bien les méthodes endoscopiques. Consulter les publications médicales relatives aux techniques, contre-indications, complications et risques avant de procéder à toute intervention endoscopique. Contacter US Endoscopy pour obtenir des informations relatives aux techniques ou contre-indications endoscopiques, si nécessaire.
- Ne pas utiliser l'aiguille à injection en cas de dommage apparent dû au transport ou à la manipulation.
- Ces aiguilles à injection sont compatibles avec les canaux d'endoscope d'au moins 2,8 mm de diamètre.
- Pour les aiguilles à injection Carr-Locke uniquement : Ne pas essayer d'actionner l'aiguille à injection avec le cathéter en position redressée. L'aiguille à injection a été conçue et fabriquée avec un « pré-chargement » spécifique qui est nécessaire afin d'assurer la projection et le retrait complets de l'aiguille du pivot distal lors de configurations très tortueuses. Si l'aiguille à injection est actionnée avec le cathéter en position redressée, le « pré-chargement » peut entraîner la chute du cathéter interne de l'aiguille et ne pas permettre une injection adéquate. Lors de la manipulation de l'aiguille à injection, toujours avoir son extrémité distale présente à l'esprit et confirmer visuellement que l'aiguille est entièrement rétractée dans le dispositif.
- Pour les aiguilles à injection Vari-Safe™ uniquement : Ne pas essayer d'activer ou de tester l'aiguille à injection hors de l'endoscope si le dispositif est enroulé à plusieurs reprises. Il est possible que l'aiguille à injection se retrouve en position proximale par rapport au ressort de l'extrémité distale.
- Ces aiguilles à injection sont des dispositifs médicaux jetables à usage unique qui ne doivent pas être réutilisés. Tout établissement, praticien ou tiers qui retraite, rénove, transforme, restérilise et/ou réutilise ces dispositifs jetables est entièrement responsable de leur sécurité et efficacité.
- Toutes les aiguilles à injection mentionnées dans ce mode d'emploi sont compatibles avec les solutions et substances médicinales suivantes : morrhuate de sodium, tétradécyl sulfate de sodium, oléate d'éthanolamine, épinéphrine, Botox, polidocanol, éthanol, Sotradecol, alcool absolu, encre de Chine, solution saline hypertonique et milieu de coloration.
- En outre, il a été confirmé que les aiguilles à injection Vari-Safe™ (réf. produit 00711818, 00711819 et 00711820) sont compatibles avec Triamcinolone (Kenalog). La compatibilité avec d'autres substances n'a pas été vérifiée et leur utilisation est donc déconseillée.
- Contrairement à l'aiguille à injection Carr-Locke (réf. produit 00711813), les aiguilles à injection Carr-Locke et Articulator™ (réf. produit 00711811, 00711803, 00711804, 00711807 et 0071808) ne sont pas compatibles avec les gastroscopes haute définition Pentax modèles 90.

Contre-indications : L'utilisation de ce dispositif est contre-indiquée pour les patients non coopératifs et/ou les coagulopathies aiguës.

Mode d'emploi :

1. (a) Pour les aiguilles à injection Articulator™ et Carr-Locke uniquement : Retirer soigneusement la protection de l'extrémité distale de l'aiguille. Actionner le luer proximal d'arrière en avant, puis observer visuellement l'aiguille qui doit être correctement avancée depuis l'extrémité distale du dispositif. La poignée à ressort facilite la rétraction de l'aiguille. Toutefois, ce mouvement doit toujours être contrôlé visuellement. (Remarque : le produit version n° 00711808 utilisé pour l'entéroscopie n'est pas doté de cette fonction de poignée à ressort.)
   (b) Pour l'utilisation des aiguilles à injection Carr-Locke dans un duodénoscope : Lors de l'utilisation de ce type d'aiguille dans un duodénoscope, avant d'actionner l'élévateur en position complète, s'assurer que la gaine de l'aiguille est adéquatement projetée au-delà de l'extrémité de l'appareil afin d'éviter d'endommager l'aiguille qui, en position rétractée, est positionnée à l'intérieur du ressort proximal par rapport à l'extrémité distale.
   (c) Pour les aiguilles à injection Vari-Safe™ uniquement : L'aiguille est expédiée en position « aiguille projetée ». Cela évite que l'aiguille distale soit prise sur le ressort distal. Retirer soigneusement la protection de l'extrémité distale de l'aiguille. Dérouler la gaine de l'aiguille et s'assurer que l'aiguille est correctement projetée. Déverrouiller le raccord Luer-Lock et actionner le luer proximal d'arrière en avant, et veiller à ce que l'aiguille soit correctement avancée depuis l'extrémité distale. Le ressort de rappel facilite la rétraction de l'aiguille. Toutefois, ce mouvement doit toujours être contrôlé visuellement.
   Remarque : ne pas étirer le dispositif car cela pourrait modifier la longueur de projection de l'aiguille.
2. Pour verrouiller l'aiguille en position extérieure, appuyer doucement sur le luer proximal jusqu'à ce qu'il rencontre le luer de la poignée, puis tourner doucement le luer proximal dans le sens des aiguilles d'une montre jusqu'à ce que les deux luers soient entièrement enclenchés.
3. En utilisant des méthodes médicales acceptées, expirer l'air de l'aiguille à l'aide du support d'injection.
4. S'assurer que l'aiguille est entièrement rétractée avant de l'insérer dans l'endoscope.
5. Poursuivre en procédant à l'injection du support adéquat, en utilisant des techniques médicales approuvées, jusqu'à l'obtention des résultats souhaités.
6. Lors du passage d'un site d'injection au suivant, il est conseillé de rétracter l'aiguille dans la gaine afin de protéger la muqueuse, ainsi que l'endoscope, de tout endommagement/traumatisme.
7. Lors du retrait de l'aiguille à injection de l'endoscope, rétracter entièrement l'aiguille dans la gaine afin de protéger le patient et le médecin contre toute blessure et éviter tout endommagement potentiel de l'endoscope.

Mise au rebut du produit :
Après utilisation, ce produit peut être considéré comme un déchet biologique potentiellement toxique. Il doit être manipulé et mis au rebut conformément aux pratiques médicales courantes et à la législation et aux recommandations en vigueur à l'échelon local, national et communautaire.

Date d'émission : Octobre 2008

Avertissement :
La date d'émission ou de révision de ces instructions est incluse à titre d'information de l'utilisateur. Si deux années se sont écoulées entre cette date et l'utilisation du produit, contacter US Endoscopy pour déterminer si des informations supplémentaires sont disponibles.

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Ce produit et/ou son utilisation sont protégés par le brevet américain n° 6.666.847.
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00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Verwendungszweck:
Diese Einweg-Injektionsnadeln mit flexibler dienen zur Injektion verschiedener Flüssigkeiten durch ein flexibles Endoskop.

Warn- und Vorsichtshinweise:

- Flexible Endoskopieverfahren sind nur von entsprechend geschulten Personen mit Erfahrung bezüglich der Techniken der Endoskopie einzusetzen. Vor der Durchführung jeglicher endoskopischer Verfahren in der medizinischen Fachliteratur bezüglich Methodik, Kontraindikationen, Komplikationen und Risiken nachlesen. Bei Bedarf an Referenzinformationen zu endoskopischen Methoden und Kontraindikationen wenden Sie sich bitte an US Endoscopy.
- Injektionsnadeln nicht verwenden, falls offensichtliche Transport- oder sonstige Schäden zu erkennen sind.
- Die Injektionsnadeln sind kompatibel mit einem endoskopischen Kanal von mindestens 2,8 mm.
- **Nur für Carr-Locke-Injektionsnadeln:** Bei überstrecktem Katheter darf die Injektionsnadel nicht betätigt werden. Die Injektionsnadel wurde mit einer spezifischen „Vorspannung" konzipiert und gefertigt, um auch bei sehr gewundenen Strukturen einen vollständigen Vorschub und ein vollständiges Rückziehen der Nadel aus dem distalen Ende zu gewährleisten. Bei Betätigung der Injektionsnadel mit einem überstrecktem Katheter kann es durch die erwähnte Vorspannung zu einem Zusammenfallen des Innenkatheters der Injektionsnadel kommen; eine adäquate Injektion ist dann nicht mehr möglich. Beim Umgang mit der Injektionsnadel stets auf die distale Spitze der Nadel achten und durch Sichtkontrolle gewährleisten, daß die Nadel vollständig eingezogen ist.
- **Nur für Vari-Safe™-Injektionsnadeln:** Eine Betätigung oder ein Testen der Injektionsnadel außerhalb des Endoskops (falls mehrmals gewunden) ist unzulässig, da es dadurch zu einem proximalen Verkanten der Nadel an der Feder der distalen Spitze kommen kann.
- Diese medizinischen Einweg-Injektionsnadeln sind nicht zur Wiederverwendung geeignet. Jede Einrichtung, jeder praktische Arzt und jede dritte Partei, die die beschriebenen Einwegprodukte wiederverarbeitet, aufarbeitet, umarbeitet, resterilisiert und/oder wiederverwendet, trägt die volle Verantwortung für deren Sicherheit und Wirksamkeit.
- Alle Injektionsnadeln, die in dieser Gebrauchsanweisung berücksichtigt sind, sind mit den folgenden medizinischen Substanzen und Lösungen kompatibel: Natriummorrhuat, Natrium-Tetradecylsulfat, Ethynolaminoleat, Epinephrin, Botox, Polidocanol, Ethanol, Sotradecol, absoluter Alkohol, India-Ink-Farbstoff, hypertonische Kochsalzlösung und Farbmarkierungsmittel.
- Außerdem wurde bestätigt, dass die Vari-Safe™-Injektionsnadeln (Produktnummer 00711818, 00711819 und 00711820) kompatibel mit Triamcinolon (Kenalog) sind. Die Kompatibilität mit anderen Substanzen ist nicht verifiziert, weshalb sie nicht in Betracht gezogen werden sollten.
- Die Carr-Locke- und Articulator™-Injektionsnadeln mit den Produktnummern 00711811, 00711803, 00711804, 00711807 und 00711808 sind nicht mit Pentax-Gastroskopen der Serie High Definition (Modell 90) kompatibel. Dahingegen können die Carr-Locke-Injektionsnadeln mit der Produktnummer 00711813 zusammen mit den Pentax-Gastroskopen der Serie High Definition (Modell 90) verwendet werden.

Kontraindikationen: Die Verwendung dieses Produkts ist kontraindiziert bei unkooperativen Patienten und/oder Patienten mit schwerer Koagulopathie.

Gebrauchsanleitung:

1. (a) **Nur für Articulator™- und Carr-Locke-Injektionsnadeln:** Den Spitzenschutz vorsichtig von der distalen Spitze der Nadel abnehmen. Den proximalen Luer-Anschluss vor- und zurückbewegen und durch Sichtprüfung feststellen, ob sich die Nadel korrekt aus dem distalen Ende herausbewegt. Der gefederte Griff unterstützt das Einziehen der Nadel; der Einzug jedoch stets auch visuell prüfen. (Anmerkung: Produkt Nr. 00711808 verfügt in der zu endoskopischen Zwecken verwendeten Version nicht über die beschriebene Federung des Griffs.)
   (b) Für die Verwendung von Carr-Locke-Injektionsnadeln in einem Duodenoskop: Bei der Verwendung der Nadel in einem Duodenoskop muss vor der Betätigung des Elevators in die volle Position darauf geachtet werden, dass die Nadelhülle ausreichend am Ende des Sichtgeräts vorbeigeschoben ist, um eine Beschädigung der Nadel, die sich in der eingezogenen Stellung in der Feder proximal zur distalen Spitze befindet, zu vermeiden.
   (c) Nur für Vari-Safe™-Injektionsnadeln: Geliefert wird die Nadel in einer „Nadelschutzstellung". Dies ist erforderlich, um ein Verfangen zwischen der distalen Nadel und der distalen Feder zu vermeiden. Den Spitzenschutz vorsichtig von der distalen Spitze der Nadel abnehmen.
   Die Nadelhülle abwickeln und gewährleisten, dass die Nadel korrekt vorsteht. Den Luer-Anschluss entsperren, den proximalen Luer-Anschluss vor- und zurückbewegen und durch Sichtprüfung feststellen, ob sich die Nadel korrekt aus dem distalen Ende herausbewegt. Die Rückholfeder unterstützt das Einziehen der Nadel; der Einzug muss jedoch stets auch visuell überprüft werden.
   Anmerkung: Jedes Überdehnen des Produkts vermeiden, da es dadurch zu einer Änderung der Nadelvorstandslänge kommen kann.
2. Zur Sicherung der Nadel in vorstehender Stellung leicht auf den proximalen Luer-Anschluss drücken, bis er am Griff anliegt; dann den proximalen Luer-Anschluss langsam im Uhrzeigersinn drehen, bis beide Luer-Anschlüsse vollständig einrasten.
3. Unter Verwendung gängiger medizinischer Methoden das Nadelset mit der Injektionsflüssigkeit vorfüllen.
4. Vor dem Einführen in das Endoskop muss die Nadel vollständig eingezogen sein.
5. Unter Verwendung anerkannter medizinischer Methoden die Injektion der entsprechenden Flüssigkeiten durchführen, bis das gewünschte Ergebnis erzielt wurde.
6. Beim Wechsel von einem Injektionsort zum nächsten wird ein Zurückziehen der Nadel in die Hülle empfohlen, um die Mucosa vor Trauma zu schützen und Beschädigungen des Endoskops zu vermeiden.
7. Beim Entfernen der Injektionsnadel aus dem Endoskop auf vollständiges Einziehen der Nadel in die Hülle achten, um den Patienten und den behandelnden Chirurgen vor Verletzungen zu schützen und Beschädigungen des Endoskops zu vermeiden.

Entsorgung des Produkts:
Nach Gebrauch ist dieses Produkt eine potenzielle biologische Gefahrenquelle. Das Produkt ist daher gemäß der gängigen medizinischen Praxis sowie den örtlich, landesweit und bundesweit geltenden gesetzlichen Bestimmungen und Regelungen zu handhaben und entsorgen.

Veröffentlichungsdatum: Oktober 2008

Warnhinweis:
Die Gebrauchsanleitung ist zu Informationszwecken mit einem Veröffentlichungs- bzw. Revisionsdatum versehen. Falls zwischen dem angegebenen Datum und dem Verwendungszeitpunkt des Produkts zwei Jahre vergangen sind, sollte der Anwender US Endoscopy kontaktieren, um zu erfahren, ob zusätzliche Informationen verfügbar sind.

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Das vorliegende Produkt und/oder seine Verwendung ist geschützt durch US-Patentnummer 6,666,847.

Hergestellt in den USA

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Uso previsto:
Gli aghi per iniezione e introduttori flessibili monouso sono progettati per l'iniezione di vari tipi di liquidi attraverso endoscopi flessibili.

Avvertenze e precauzioni:

- Le procedure con endoscopio flessibile devono essere eseguite da personale medico con un'adeguata conoscenza e familiarità con le tecniche endoscopiche. Prima di intraprendere qualsiasi procedura endoscopica, consultare la letteratura medica relativa alle tecniche, alle controindicazioni, alle complicazioni e ai rischi relativi. Per informazioni sulle tecniche endoscopiche o le controindicazioni, contattare US Endoscopy.
- Non utilizzare l'ago per iniezione in caso di danni subiti durante la spedizione o la manipolazione.
- Questi aghi per iniezione sono compatibili con endoscopi con canali di almeno 2,8 mm di diametro.
- Esclusivamente per aghi per iniezione Carr-Locke: non tentare di utilizzare l'ago per iniezione se il catetere è in posizione dritta. L'ago per iniezione è stato progettato e prodotto con una specifica "precarica", necessaria per garantire la sua completa protezione e retrazione dalla posizione distale quando il dispositivo si trova in configurazioni tortuose. Se l'ago per iniezione è utilizzato con il catetere dritto, la "precarica" può provocare il collasso del catetere interno dell'ago e un'iniezione inadeguata. Durante l'utilizzo dell'ago per iniezione, prestare sempre attenzione alla posizione dell'estremità distale dell'ago e accertarsi visivamente che l'ago sia completamente retratto nel dispositivo.
- Esclusivamente per aghi per iniezione Vari-Safe™: non tentare di mettere in funzione o testare l'ago per iniezione fuori dall'endoscopio, se il dispositivo presenta più di un avvolgimento, poiché l'ago per iniezione potrebbe bloccarsi a livello della molla dell'estremità distale.
- Questi aghi per iniezione sono dispositivi monouso che devono essere smaltiti dopo il primo uso. Qualsiasi istituto, professionista o terzi che tratti nuovamente, rinnovi, ricostruisca, risterilizzi e/o riusi questi dispositivi monouso, è completamente responsabile della sicurezza e dell'efficienza degli stessi.
- Tutti gli aghi per iniezione inclusi in queste istruzioni per l'uso sono compatibili con i seguenti farmaci e soluzioni: sodio morruato, sodio tetradecilsolfato, etinolammina oleato, opinefrina, Botox, polidocanolo, etanolo, Sotradecol, alcool assoluto, inchiostro indiano, soluzione salina ipertonica e mezzi di colorazione.
- In aggiunta, gli aghi per iniezione Vari-Safe™ (prodotti 00711818, 00711819 e 00711820) sono stati dichiarati compatibili con il Triamcinolone (Kenalog). Non è stata verificata la compatibilità con altre sostanze, pertanto è sconsigliato il loro utilizzo.
- Gli aghi per iniezione Carr-Locke e Articulator™ (prodotti 00711811, 00711803, 00711804, 00711807 e 0071808) sono stati dichiarati non compatibili con i gastroscopi Pentax 90 Series ad alta definizione, mentre l'ago per iniezione Carr-Locke (prodotto 00711813) è compatibile con i gastroscopi Pentax 90 Series ad alta definizione.

Controindicazioni: l'utilizzo di questo dispositivo è controindicato con pazienti non cooperativi e/o con coagulopatia grave.

Istruzioni per l'uso:

1. (a) Esclusivamente per aghi per iniezione Articulator™ e Carr-Locke: rimuovere con attenzione la protezione della punta dalla porzione distale dell'ago. Muovere avanti e indietro il luer prossimale e controllare visivamente che l'ago avanzi adeguatamente dall'estremità distale del dispositivo. L'impugnatura con carica a molla facilita la retrazione dell'ago che però va sempre controllata anche visivamente. (Nota: la versione n. 00711808 del prodotto, utilizzata per enteroscopia, non è dotata dell'impugnatura con carica a molla).
   (b) Per l'uso dell'ago per iniezione Carr-Locke in un duodenoscopio: quando si usa questo ago in un duodenoscopio, prima di azionare completamente lo stantuffo, controllare che l'introduttore sia ben oltre l'estremità dello scopio per evitare di danneggiare l'ago che, in posizione retratta, si trova all'interno della molla prossimale all'estremità distale.
   (c) Esclusivamente per aghi per iniezione Vari-Safe™: l'ago viene spedito in posizione "sporgente". Ciò è necessario per evitare che la porzione distale dell'ago si impigli nella molla distale. Rimuovere con attenzione la protezione della punta dalla porzione distale dell'ago. Svolgere l'introduttore dell'ago e assicurare che l'ago sporga adeguatamente. Sbloccare il luer lock prossimale e muovere avanti e indietro il luer prossimale controllando visivamente che l'ago avanzi adeguatamente dall'estremità distale. La molla con ritorno facilita la retrazione dell'ago che, però, va sempre controllata anche visivamente.
   Nota: non tirare il dispositivo, poiché ciò potrebbe modificare la sporgenza dell'ago.
2. Per bloccare l'ago nella posizione esterna, premere delicatamente il luer prossimale fino a porlo in contatto con il luer dell'impugnatura, quindi farlo ruotare lentamente fino a innestare completamente i due raccordi.
3. Con le metodiche standard, eliminare l'aria contenuta nel gruppo ago con il liquido d'iniezione.
4. Controllare che l'ago sia completamente retratto, prima di inserirlo nell'endoscopio.
5. Procedere con l'iniezione del liquido adeguato secondo le tecniche approvate sino a ottenere il risultato atteso.
6. Quando si cambia sito di iniezione, si consiglia di ritirare l'ago nell'introduttore per proteggere la mucosa e l'endoscopio da possibili traumi/danni.
7. Quando si rimuove l'ago per iniezione dall'endoscopio, ritirare completamente l'ago nell'introduttore per proteggere il paziente e il medico da possibili lesioni e l'endoscopio da possibili danni.

Smaltimento del dispositivo:
Dopo l'uso, il prodotto è potenzialmente a rischio biologico. Maneggiarlo e smaltirlo secondo le pratiche mediche accettate e le normative nazionali e locali in vigore.

Data di distribuzione: Ottobre 2008

Avvertenza:
Per informazione dell'utente viene indicata la data di distribuzione o di revisione di queste istruzioni. Nel caso in cui siano trascorsi due anni tra questa data e l'uso del prodotto, l'operatore deve contattare la US Endoscopy per sapere se sono disponibili ulteriori informazioni.

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Questo prodotto e/o l'uso del prodotto è protetto dal numero di brevetto 6.666.847 depositato negli Stati Uniti.

Fabbricato negli U.S.A.
00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-6118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Uso previsto:
Las agujas de inyección en vaina flexible de un solo uso están diseñadas para la inyección de varios tipos de medios a través de un endoscopio flexible.

Advertencias y precauciones:

- La endoscopia flexible debe realizarse sólo por personal con la adecuada formación y familiarizado con las técnicas correspondientes. Antes de realizar cualquier procedimiento endoscópico, consulte en la literatura médica sus técnicas, contraindicaciones, y riesgos. Si necesita información de referencia sobre la técnica endoscópica o sus contraindicaciones, llame a US Endoscopy.
- No use esta aguja de inyección si observa daños ocasionados durante el envío o la manipulación del producto.
- Estas agujas de inyección son compatibles con un canal de endoscopia de 2,8 mm o mayor.
- Solamente para las agujas de inyección Carr-Locke: No intente manipular la aguja de inyección con el catéter en posición recta. La aguja de inyección se ha diseñado y fabricado con una "precarga" específica que es necesaria para conseguir la proyección y retracción completas de la aguja desde el conector distal cuando el dispositivo se use en configuraciones muy tortuosas. Si la aguja de inyección actúa con el catéter en posición recta, la "precarga" puede hacer que el catéter interno de la aguja se colapse y no permita la inyección. Al manipular la aguja de inyección, compruebe siempre su punta distal y que la aguja esté totalmente retraída en el dispositivo.
- Solamente para las agujas de inyección Vari-Safe™: No intente manipular o probar la aguja de inyección fuera del endoscopio si el dispositivo se enrolla más de una vez. Es posible que esto haga que la aguja de inyección quede alojada proximal al muelle de la punta distal.
- Estas agujas de inyección son de un solo uso; son dispositivos médicos desechables y no son reutilizables. Cualquier centro, médico o tercera persona que reprocese, restaure o vuelva a elaborar, esterilizar o utilizar estos dispositivos desechables tendrá toda la responsabilidad sobre su seguridad y eficacia.
- Todas las agujas de inyección incluidas en estas instrucciones de uso son compatibles con las siguientes sustancias y soluciones: morruato sódico, tetradecilsulfato sódico, oleato de etinolamina, epinefrina, botox, polidocanol, etanol, sotradecol, alcohol absoluto, tinta china, solución salina hipertónica y medios de contraste.
- Además, se ha confirmado que las agujas de inyección Vari-Safe™ (números de producto 00711818, 00711819 y 00711820) son compatibles con Triamcinolone (Kenalog). No se ha verificado la compatibilidad de otras sustancias y, por tanto, no deberá intentarse.
- Las agujas de inyección Carr-Locke y Articulator™ (números de producto 00711811, 00711803, 00711804, 00711807 y 0071808) no son compatibles con los gastroscopios de alta definición Pentax Modelo 90, mientras que la aguja de inyección Carr-Locke (número de producto 00711813) sí es compatible con los gastroscopios de alta definición Pentax Modelo 90.

Contraindicaciones: El uso de este dispositivo está contraindicado en pacientes no colaboradores y pacientes con coagulopatía grave.

Instrucciones de uso:

1. (a) Solamente para las agujas de inyección Articulator™ y Carr-Locke: Extraiga con cuidado el protector de la punta distal de la aguja. Mueva el luer proximal adelante y atrás y observe que la aguja avanza correctamente desde el extremo distal del dispositivo. El mango de carga con resorte facilita la retracción de la aguja; sin embargo, compruebe siempre manualmente la retracción. (Nota: la versión del producto 00711808 que se usa en la enteroscopia no cuenta con este mango de carga con resorte.)
   (b) Para la aguja de inyección Carr-Locke utilizada en un duodenoscopio: Cuando use esta aguja en un duodenoscopio compruebe que la vaina de la aguja se proyecta correctamente hasta atravesar el extremo del endoscopio antes de manipular el elevador en la posición completa, para evitar daños a la aguja que, en la posición retraída, se encuentra dentro del muelle proximal a la punta distal.
   (c) Solamente para las agujas Vari Safe™: La aguja se envía en una posición de "aguja proyectada". Esto es necesario para evitar que la aguja distal quede atrapada en el muelle distal. Extraiga con cuidado el protector de la punta distal de la aguja. Desenrolle la vaina de la aguja y compruebe que la aguja está proyectada debidamente. Desbloquee el cierre luer y mueva el luer proximal hacia delante y atrás y observe que la aguja avanza correctamente desde el extremo distal. El muelle de retorno facilita la retracción de la aguja; sin embargo, compruebe siempre manualmente la retracción.
   Nota: No estire el dispositivo porque puede alterar la longitud de proyección de la aguja.
2. Para bloquear la aguja en la posición de salida, presione suavemente el luer proximal hasta que llegue al mango luer y después, lentamente, gire el luer proximal en dirección de las agujas del reloj hasta que los dos cierres luer encajen perfectamente.
3. Purgue el aire del montaje de la aguja con un medio de inyección según los métodos estándar.
4. Compruebe que la aguja está totalmente retraída antes de insertarla en el endoscopio.
5. Continúe con la inyección del medio apropiado usando la técnica médica aprobada hasta conseguir los resultados deseados.
6. Cuando pase de un punto de inyección al siguiente, se aconseja retraer la aguja en la vaina para proteger la mucosa y el endoscopio de posibles traumatismos o daños.
7. Cuando extraiga la aguja de inyección del endoscopio, retraiga la aguja completamente en la vaina para proteger al paciente y al médico de posibles lesiones y al endoscopio de posibles daños.

Eliminación del producto:
Después de su uso, este producto puede representar un posible riesgo biológico. Manipúlelo y deséchelo según la práctica médica habitual y las leyes y normativas locales, estatales y federales aplicables.

Fecha de emisión: Octubre de 2008

Advertencia:
Para información del usuario, se incluye la fecha de emisión o revisión de estas instrucciones. Contactar con US Endoscopy en caso de que hayan transcurrido dos años entre esta fecha y la de uso del producto, por si hubiera nueva información.

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Esto producto así como su uso están protegidos bajo el número de patente estadounidense 6,666,847.

Fabricado en EE. UU.

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Indicação de Utilização:
Estas agulhas de injecção de bainha flexível descartável e de utilização única destinam-se a ser utilizadas para a injecção de vários tipos de meios através endoscópios flexíveis.

Avisos e Precauções:

- Os procedimentos endoscópicos flexíveis devem ser realizados apenas por pessoas com a formação adequada e que estejam familiarizadas com as técnicas endoscópicas. Consultar a literatura médica relativamente às técnicas, contra-indicações, complicações e perigos antes de iniciar qualquer procedimento endoscópico. Se for necessária informação de referência relativa a técnicas endoscópicas ou a contra-indicações contacte a US Endoscopy.
- Não utilizar uma agulha de injecção se for visível qualquer dano de transporte ou de manuseamento.
- Estas agulhas de injecção são compatíveis com um canal endoscópico de 2,8 mm ou maior.
- Apenas para agulhas de injecção Carr-Locke: Não tentar mover a agulha de injecção com o cateter em posição direita. A agulha de injecção foi concebida e fabricada com uma "pré-carga" específica, necessária para assegurar a projecção completa e a retracção completa da agulha a partir da manga distal quando o dispositivo se encontra em configurações muito tortuosas. Se a agulha de injecção for movida com o cateter numa posição direita, a "pré-carga" pode provocar o colapso do cateter interior da agulha e não permitir a injecção adequada. Ao manusear a agulha
de injecção, tenha sempre em vista a sua ponta distal e confirme visualmente que a agulha está completamente retraída dentro do dispositivo.
- Apenas para agulhas de injecção Vari-Safe™: Não tentar activar ou testar a agulha de injecção fora do endoscópio se se encontrar enrolado mais do que uma vez. É possível que isto faça com que a agulha fique alojada proximalmente à mola da ponta distal.
- Estas agulhas de injecção são dispositivos médicos descartáveis de utilização única; não se destinam à reutilização. Qualquer instituição, médico ou terceiro que volte a processar, renovar, fabricar, esterilizar e/ou reutilizar estes dispositivos descartáveis tem que assumir total responsabilidade pela sua segurança e eficácia.
- Todas as agulhas de injecção incluídas nestas Instruções de Utilização são compatíveis com as seguintes substâncias e soluções medicinais: Morruato de sódio, tetradecilsulfato de sódio, oleato de etanolamina, epinefrina, botox, polidocanol, etanol, solradecol, álcool absoluto, tinta da Índia, solução salina hipertónica, meios de coloração.
- Além disso, comprovou-se que as agulhas de injecção Vari-Safe™ (produto n.º 00711818, 00711819 e 00711820) são compatíveis com Triamcinolona (Kenalog). A compatibilidade com outras substâncias não foi verificada e por isso não deve ser experimentada.
- As agulhas de injecção Carr-Locke e Articulator™ (produtos nº 00711811, 00711803, 00711804, 00711807 e 0071808) não são compatíveis com os gastroscópios de Alta Definição Pentax Model séries 90, enquanto a agulha de injecção Carr-Locke (produto nº 00711813) é compatível com os gastroscópios de Alta Definição Pentax Model série 90 series.

Contra-Indicações: A utilização deste dispositivo é contra-indicada em pacientes não cooperantes e/ou em pacientes com coagulopatia aguda.

Instruções de Utilização:

1. (a) Apenas para agulhas de injecção Articulator™ e Carr-Locke: Remova cuidadosamente o protector de ponta da ponta distal da agulha. Movimente o luer proximal para trás e para a frente, observando a agulha a avançar adequadamente a partir da extremidade distal do dispositivo. A pega accionada por mola auxilia na retracção da agulha; no entanto, deve verificar também sempre manualmente a retracção. (Nota: A versão do produto n.º 00711808 utilizada para a enteroscopia não possui a função de pega accionada por mola.)
   (b) Apenas para a utilização de agulhas de injecção Carr-Locke num duodenoscópio: Ao utilizar uma agulha num duodenoscópio, antes de mover o elevador para a posição cheia, assegure que a bainha da agulha é adequadamente projectada para lá da extremidade do endoscópio para evitar danos na agulha que, na posição retraída, é posicionada dentro da mola proximal à ponta distal.
   (c) Apenas para agulhas de injecção Vari Safe™: A agulha foi expedida na posição de "agulha projectada". Isto é necessário para manter a agulha distal afastada da mola distal. Remova cuidadosamente o protector de ponta da ponta distal da agulha. Desenrole a bainha da agulha e certifique-se que a agulha é projectada correctamente. Desbloqueie o conector luer lock e movimente o luer proximal para trás e para a frente, observando a agulha a avançar adequadamente a partir da extremidade distal. A mola de retorno auxilia na retracção da agulha; no entanto, deve verificar também sempre manualmente a retracção.
   Nota: Não estique o dispositivo; tal poderá alterar o comprimento de projecção da agulha.
2. Para bloquear a agulha na posição saída, pressione ligeiramente o luer proximal até encontrar o luer da pega e, de seguida, rode lentamente o luer proximal no sentido dos ponteiros do relógio até os dois luers estarem completamente encaixados.
3. Utilizando métodos médicos aceites, purgue o ar do conjunto da agulha com o meio de injecção.
4. Certifique-se que a agulha está completamente retraída antes de a insair no endoscópio.
5. Prossiga com a injecção de um meio apropriado utilizando técnicas médicas aprovadas até serem alcançados os resultados pretendidos.
6. Ao mover de um local de injecção para o próximo, é aconselhável retrair a agulha para dentro da bainha para proteger a mucosa, assim como o endoscópio de trauma/danos.
7. Ao remover a agulha de injecção do endoscópio, retraia completamente a agulha para dentro da bainha para proteger o paciente e o médico de ferimentos e para proteger o endoscópio de danos potenciais.

Eliminação do Produto:
Depois de utilizado, este produto pode representar um risco biológico potencial. Manusear e eliminar em conformidade com a prática médica padrão e com as regulamentações e leis locais, federais e estatais aplicáveis.

Data de Emissão: Outubro 2008

Aviso:
É incluída uma data de emissão ou de revisão para estas instruções para informação do utilizador. Caso passem dois anos entre esta data e a utilização do produto, o utilizador deve contactar a US Endoscopy para determinar se é necessária informação adicional.

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Este produto e/ou a sua utilização está protegido pela patente nº 6.666.847 dos E.U.A.
Fabricado nos E.U.A.

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO LATEX Rx Only (U.S.A.)

Tilsigtet anvendelse:
De fleksible hylsterinjektionsnåle til engangsbrug er beregnet til injektion af forskellige typer medie gennem fleksible endoskoper.

Advarsler og forholdsregler:

- Procedurer for fleksibel endoskopi bør kun udføres af personer med den fornødne uddannelse og kendskab til endoskopiske teknikker. Konsulter den medicinske litteratur vedrørende teknikker, kontraindikationer, komplikationer og risici forud for den endoskopiske procedure. Kontakt US Endoscopy for at få referenceoplysninger vedrørende endoskopiske teknikker eller kontraindikationer.
- Brug ikke en injektionsnål, hvis den har taget synlig skade under transporten eller håndteringen.
- Injektionsnålene er kompatible med endoskopkanaler på 2,8 mm eller større.
- **Kun til Carr-Locke-injektionsnåle:** Forsøg ikke at aktivere injektionsnålen, når kateteret er i udstrakt position. Injektionsnålen er udviklet og fremstillet med en bestemt "forspænding", som er nødvendig for at sikre fuld projektion og fuld tilbagetrækning af nålen fra den distale muffe, når anordningen er i forbindelse med meget snoede konfigurationer. Hvis injektionsnålen aktiveres, mens kateteret er i udstrakt position, kan "forspændingen" medføre, at nålens indvendige kateter bryder sammen, så der ikke kan foretages en tilstrækkelig injektion. Ved håndtering af injektionsnålen er det vigtigt altid at være opmærksom på nålens distale studs og visuelt bekræfte, at nålen er trukket helt tilbage i anordningen.
- **Kun til Vari-Safe™-injektionsnåle:** Forsøg ikke at aktivere eller afprøve injektionsnålen uden for endoskopet, hvis anordningen er snoet mere end én gang. Injektionsnålen kan sætte sig fast proksimalt i forhold til fjederen i den distale studs.
- Disse injektionsnåle er medicinske anordninger til engangsbrug og er ikke beregnet til genbrug. Institutioner, læger eller tredjeparter, der genbehandler, genfremstiller, gensteriliserer, genbruger og/eller poterer disse engangsanordninger op bærer det fulde ansvar for deres sikkerhed og effektivitet.
- **Samtlige injektionsnåle, der er inkluderet i denne IFU (brugsanvisning), er kompatible med følgende medicinske stoffer og opløsninger: Natriummorrhuat, natriumtetradecylsulfat, ethynolaminoleat, epinefrin, botox, polidocanol, ethanol, sotradecol, absolut alkohol, tusch, hypertonisk salt og farvningsmedier.**
- Hertil kommer, at det er blevet bekræftet, at Vari-Safe™-injektionsnåle (produktnr. 00711818, 00711819 og 00711820) er kompatible med Triamcinolon (Kenalog). Kompatibilitet med andre stoffer er ikke bekræftet, og sådanne bør derfor ikke anvendes.
- **Carr-Locke- og Articulator™-injektionsnåle (produktnr. 00711811, 00711803, 00711804, 00711807 og 0071808) er ikke kompatible med Pentax Model 90-serlens gastroskoper med høj definition, mens Carr-Locke-injektionsnålen (produktnummer 00711813) er kompatibel med Pentax Model 90-serlens gastroskoper med høj definition.**

Kontraindikationer: Brug af denne anordning er kontraindiceret til usamarbejdsvillige patienter og/eller patienter med alvorlig koagulopati.

Brugsanvisning:

1. (a) **Kun til Articulator™- og Carr-Locke-injektionsnåle:** Fjern forsigtigt beskyttelseskappen fra nålens distale studs. Bevæg den proksimale luer frem og tilbage, idet det visuelt observeres, at nålen føres tilstrækkeligt frem fra anordningens distale ende. Det fjederbelastede greb hjælper med ved tilbagetrækningen af nålen, men tilbagetrækningen bør også altid kontrolleres visuelt. (Bemærk: Produktnr. 00711808, som er beregnet til enteroskopi, har ikke et fjederbelastet greb).
   (b) **Til brug med Carr-Locke-injektionsnål i et duodenoskop:** Hvis denne nål anvendes i et duodenoskop, skal du, inden du bevæger elevatoren til den fulde position, sikre, at nålehylsteret er ført tilstrækkeligt langt forbi skopets ende for at forhindre beskadigelse af nålen, der i den tilbagetrukne position er placeret inde i fjederen proksimalt i forhold til den distale studs.
   (c) **Kun til Vari-Safe™-injektionsnåle:** Ved levering er nålen i en position, hvor den er beskyttet. Dette er nødvendigt for at forhindre, at den distale nål griber fat i den distale fjeder. Fjern forsigtigt beskyttelseskappen fra nålens distale studs. Rul nålehylsteret ud, og sørg for, at nålen er ført tilstrækkelig langt frem. Friger luer-lås-koblingen, og bevæg den proksimale luer frem og tilbage, idet det visuelt observeres, at nålen føres tilstrækkeligt frem fra den distale ende. Returfjederen hjælper med ved tilbagetrækningen af nålen, men tilbagetrækningen bør altid kontrolleres visuelt.
   Bemærk: Stræk ikke anordningen, da dette kan medføre, at nålens projektionslængde ændres.
2. Nålen låses fast i den fremførte position ved at trykke let på den proksimale luer, indtil den møder grebets luer, og derefter langsomt dreje den proksimale luer med uret, indtil de to luere går helt i hak.
3. Ved hjælp af godkendte medicinske metoder renses nålesamlingen for luft med injektionsmediet.
4. Kontroller, at nålen er trukket helt tilbage, inden den føres ind i endoskopet.
5. Fortsæt med at injicere det relevante medie, idet der anvendes godkendte medicinske teknikker, indtil det ønskede resultat er opnået.
6. Når nålen flyttes fra et injektionssted til det næste, tilrådes det at trække nålen ind i hylsteret for at beskytte slimhinden og endoskopet imod trauma/beskadigelse.
7. Når injektionsnålen fjernes fra endoskopet, skal nålen trækkes helt ind i hylsteret for at forhindre skader på patienten og lægen og for at beskytte endoskopet, så det ikke beskadiges.

Bortskaffelse af produktet:
Efter anvendelsen kan dette produkt udgøre en potentiel biologisk fare. Produktet skal håndteres og bortskaffes iht. godkendt medicinsk praksis og gældende love og regulativer.

Udstedelsesdato: oktober 2008

Advarsel:
En udstedelses- eller revisionsdato for disse instruktioner er medtaget til brugerens orientering. Hvis der er gået to år fra denne dato, og til produktet bruges, skal brugeren kontakte US Endoscopy for at få at vide, om der er fremkommet yderligere oplysninger.

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Dette produkt og/eller dets brug er beskyttet i henhold til amerikansk patentnummer 6,666,847.

Fremstillet i USA.

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Gebruiksdoel:
Deze wegwerpinjectienaalden voor eenmalig gebruik met flexibele huls zijn bedoeld voor het injecteren van diverse soorten media via een flexibele endoscoop.

Waarschuwingen en voorzorgsmaatregelen:

- Ingrepen waarbij gebruik wordt gemaakt van flexibele endoscopen mogen uitsluitend worden uitgevoerd door personen die hiervoor zijn opgeleid en die bekend zijn met desbetreffende endoscopische technieken. Voorafgaand aan elke endoscopische ingreep dient medische literatuur te worden geraadpleegd met betrekking tot de desbetreffende technieken, contra-indicaties, complicaties en mogelijke gevaren. Voor eventuele achtergrondinformatie betreffende endoscopische technieken of contra-indicaties kan contact worden opgenomen met US Endoscopy.
- Gebruik een injectienaald niet indien er sprake is van enige aanwijsbare schade als gevolg van transport of hantering.
- Deze injectienaalden zijn geschikt voor gebruik in combinatie met een endoscoopkanaal van 2,8 mm of groter.
- Alleen voor Carr-Locke injectienaalden: De injectienaald mag niet worden gebruikt wanneer de katheter zich in een rechte positie bevindt. De injectienaald is ontworpen en vervaardigd met een bepaalde "voorspanning" om te kunnen garanderen dat de naald bij zeer gebogen toestand van het instrument optimaal uitsteekt en volledig kan worden teruggetrokken uit de distale hub. Indien de injectienaald wordt gebruikt wanneer de katheter zich in een rechte positie bevindt, kan de "voorspanning" ertoe leiden dat de binnenkatheter van de naald beschadigd raakt, waardoor de injectie niet op een juiste wijze kan plaatsvinden. Bij de toepassing van de injectienaald dient de gebruiker de distale tip van de naald altijd in de gaten te houden en te controleren of de naald volledig in het instrument is teruggetrokken.
- Alleen voor Vari-Safe™ injectienaalden: De injectienaald mag niet worden geactiveerd of getest buiten de endoscoop wanneer het instrument meer dan eenmaal is gewikkeld. Anders kan de injectienaald proximaal van de veer aan de distale tip komen vast te zitten.
- Deze injectienaalden zijn medische wegwerpinstrumenten voor eenmalig gebruik en zijn niet bedoeld voor hergebruik. Elke instelling, arts of derde die deze wegwerpinstrumenten opnieuw verwerkt, herstelt, opnieuw vervaardigt, steriliseert en/of hergebruikt, is volledig verantwoordelijk voor de veiligheid en werkzaamheid ervan.
- Alle injectienaalden die zijn meegeleverd met deze gebruiksaanwijzing zijn compatibel met de volgende medicinale stoffen en oplossingen: natriummorrhuaat, natrium totradecylsulfaat, ethanolamine oleaat, epinefrine, botox, polidocanol, ethanol, sotradecol, absolute alcohol, Oost-Indische inkt, hypertonische zoutoplossing en kleurstoffen.
- Bovendien is bevestigd dat de Vari-Safe™ injectienaalden (productnummers 00711818, 00711819 en 00711820) compatibel zijn met triamcinolone (Kenalog). De compatibiliteit met andere stoffen is niet getest. Deze stoffen mogen derhalve niet in combinatie met de injectienaald worden gebruikt.
- De Carr-Locke en Articulator™ injectienaalden (productnummers 00711811, 00711803, 00711804, 00711807 en 0071808) zijn niet compatibel met hoge-definitie gastroscopen van de Pentax 90-serie, terwijl de Carr-Locke injectienaald (productnummer 00711813) wel compatibel is met hoge-definitie gastroscopen van de Pentax 90-serie.

Contra-indicaties: Contra-indicaties voor het gebruik van dit instrument zijn onwilligheid van patiënten en/of ernstige coagulopathie bij patiënten.

Gebruiksaanwijzing:

1. (a) Alleen voor Articulator™ en Carr-Locke injectienaalden: Verwijder de tipbeschermer voorzichtig van de distale tip van de naald. Beweeg de proximale luer-lock naar achteren en naar voren, terwijl u visueel controleert of de naald in voldoende mate uit het distale uiteinde van het instrument wordt geschoven. De naald kan gemakkelijk worden teruggetrokken met behulp van de veerbelaste handgreep; controleer daarnaast echter altijd visueel of de naald goed is teruggetrokken. (Opmerking: Productnr. 00711808, bestemd voor enteroscopie, is niet voorzien van bovengenoemde veerbelaste handgreep.)
   (b) Voor gebruik van een Carr-Locke injectienaald in een duodenoscoop: Wanneer deze naald via een duodenoscoop wordt aangebracht, dient ervoor te worden gezorgd dat de huls van de naald voldoende uitsteekt voorbij het uiteinde van de duodenoscoop voordat de elevator volledig wordt uitgeschoven. Dit voorkomt beschadiging van de naald, die zich in teruggetrokken positie in de veer, proximaal van de distale tip, bevindt.
   (c) Alleen voor Vari-Safe™ injectienaalden: Tijdens het transport bevindt de naald zich in een "uitstekende" positie. Dit is noodzakelijk om te voorkomen dat de naald aan het distale uiteinde in de veer komt vast te zitten. Verwijder de tipbeschermer voorzichtig van de distale tip van de naald. Wikkel de huls van de naald af en zorg ervoor dat de naald voldoende uitsteekt. Open de luer-lock sluiting en beweeg de proximale luer-lock naar achteren en naar voren, terwijl u visueel controleert of de naald in voldoende mate uit het distale uiteinde wordt geschoven. De naald kan gemakkelijk worden teruggetrokken met behulp van de terugtrekveer; controleer daarnaast echter altijd visueel of de naald goed is teruggetrokken.
   Opmerking: Strek het instrument niet volledig uit, omdat hierdoor de mate waarin de naald uitsteekt, kan veranderen.
2. Om de naald in uitgeschoven positie te vergrendelen, dient u de proximale luer-lock voorzichtig in te drukken totdat deze de luer-lock van de handgreep raakt. Draai de proximale luer-lock vervolgens langzaam rechtsom totdat de twee luer-locks volledig in elkaar grijpen.
3. Reinig de naald door middel van algemeen aanvaarde medische technieken en verwijder injectiemedia met behulp van perslucht
4. Zorg ervoor dat de naald volledig is teruggetrokken alvorens deze in de endoscoop in te brengen.
5. Injecteer de desbetreffende media door middel van goedgekeurde medische technieken, totdat het gewenste resultaat is bereikt.
6. Bij verplaatsing van de ene injectieplaats naar de volgende is het aan te raden de naald terug te trekken in de huls om het slijmvlies van de patiënt, alsmede de endoscoop te beschermen tegen trauma/beschadiging.
7. Wanneer de injectienaald uit de endoscoop wordt verwijderd, dient de naald volledig te zijn teruggetrokken in de huls om letsel bij de patiënt en de arts te voorkomen en om de endoscoop te beschermen tegen mogelijke beschadiging.

Afvoer van het product:
Na gebruik kan dit product mogelijk biologische risico's met zich meebrengen. Dit product dient te worden gehanteerd en afgevoerd overeenkomstig de algemeen aanvaarde medische gebruiken en de geldende plaatselijke, landelijke en federale wetten en voorschriften.

Uitgiftedatum: Oktober 2008

Waarschuwing:
Ter informatie van de gebruiker is voor deze instructies een uitgifte- of revisiedatum aangegeven. Indien twee jaar zijn verstreken tussen de aangegeven datum en de datum van gebruik, dient de gebruiker contact op te nemen met US Endoscopy om na te gaan of er aanvullende informatie beschikbaar is.

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Dit product en/of het gebruik ervan zijn beschermd onder octrooinummer 6,666,847 in de VS.

Vervaardigd in de VS.
00730700 Rev. 0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO Rx Only (U.S.A.)

Kullanım Amacı:
Bu tek kullanımlık esnek kılıf enjeksiyon iğneleri, çeşitli maddelerin esnek endoskoplardan enjeksiyonu için kullanılmak üzere tasarlanmıştır.

Uyarılar ve Önlemler:

- Esnek endoskopi işlemi yalnızca yeterli eğitime sahip ve endoskopik teknikleri bilen kişilerce yapılmalıdır. Herhangi bir endoskopik işlemden önce tekniklere, kontrendikasyonlara, çıkabilecek sorunlara ve tehliketere ilişkin tıbbi literatüre başvurun. Endoskopik teknik veya kontrendikasyonlar konusunda referans bilgilerine ihtiyaç duyarsanız, US Endoscopy'yi arayın.
- Gözle görülen nakliyat veya kullanım hasarı varsa enjeksiyon iğnesini kullanmayın.
- Bu enjeksiyon iğneleri 2,8mm'lik veya daha geniş endoskop kanallarıyla uyumludur.
- Yalnızca Carr-Locke enjeksiyon iğneleri için: Kateter dik pozisyondayken enjeksiyon iğnesini çalıştırma girişiminde bulunmayın. Enjeksiyon iğnesi, çok eğri şekillerde iğnenin distal merkezden tam olarak takılması ve çekilmesini sağlamaya yönelik özel bir "önyükleme" ile tasarlanmış ve üretilmiştir. Enjeksiyon iğnesinin kateter dik pozisyondayken çalıştırılması durumunda, "önyükleme" iğnenin iç kateterinin çökmesine neden olabilir ve uygun şekilde enjeksiyon yapılmasını engelleyebilir. Enjeksiyon iğnesini kullanırken iğnenin distal ucunu her zaman kontrol edin ve iğnenin aletin içine tamamen çekildiğini bakarak doğrulayın.
- Yalnızca Vari-Safe™ enjeksiyon iğneleri için: Alet birden fazla kez dolanmışsa, enjeksiyon iğnesini endoskop dışında çalıştırma veya test etme girişiminde bulunmayın. Bu, enjeksiyon iğnesinin distal uç yayın proksimaline yerleşmesine neden olabilir.
- Bu enjeksiyon iğneleri tek kullanımlık tıbbi aletlerdir; tekrar kullanılmak üzere tasarlanmamıştır. Bu tek kullanımlık aletleri tekrar işleme tabi tutan, yenileyen, tekrar üreten, tekrar sterilize eden ve/veya tekrar kullanan kurum, doktor veya üçüncü taraflar alletlerin güvenlikleri ve etkileri konusunda tüm sorumluluğu üstlenmelidir.
- Bu Kullanım Kılavuzu'nda bulunan tüm enjeksiyon iğneleri aşağıdaki tıbbi madde ve solüsyonlarla uyumludur: Sodyum Morrhuata, Sodyum Tetradesil sülfat, Etinolamin Olit, Epinefrin, Botoks, Polidokanol, Etanol, Sotradekol, Saf Alkol, Hint Mürekkebi, Hipertonik Tuz ve Boyama Maddeleri.
- Ayrıca, Vari-Safe™ enjeksiyon iğnelerinin (00711818, 00711819 ve 00711820 numaralı ürünler) Triamsinolon (Kenalog) ile uyumlu olduğu onaylanmıştır. Diğer maddeler, uyumlulukları doğrulanmadığından denenmemelidir.
- Carr-Locke ve Articulator™ enjeksiyon iğneleri (00711811, 00711803, 00711804, 00711807 ve 0071808 numaralı ürünler) Pentax Model 90 serisi Yüksek Çözünürlüklü gastroskoplarla uyumlu değildir, ancak Carr-Locke enjeksiyon iğnesi (00711813 numaralı ürün) Pentax Model 90 serisi Yüksek Çözünürlüklü gastroskoplarla uyumludur.

Kontrendikasyonlar: Bu aletin kullanımı işbirliği yapmayan hastalarda ve/veya şiddetli koagülopatide kontrendikedir.

Kullanım Talimatları:

1. (a) Yalnızca Articulator™ ve Carr-Locke Enjeksiyon İğneleri için: Uç koruyucuyu iğnenin distal ucundan dikkatli bir şekilde çıkarın. Proksimal luer ileri-geri çalıştırarak iğnenin distal uçtan uygun şekilde ilerlediğini gözlemleyin. Yayılı tutamak iğnenin geri çekilmesine yardımcı olur; ancak çekilmeyi her zaman gözle de kontrol edin. (Not: Enteroskopi için kullanılan 00711808 numaralı ürün versiyonunun yayılı tutamak özelliği yoktur.)
   (b) Carr-Locke Enjeksiyon İğnesinin Duodenoskopta Kullanımı: Bu iğneyi bir duodenoskopta kullanırken, yükselticiyi tam pozisyonuna getirmeden önce, çekilmiş durumdayken distal ucun proksimalindeki yayın içinde duran iğneye zarar gelmesini engellemek için iğne kılıfının alanın son kısmını geçecek şekilde uygun olarak takıldığından emin olun.
   (c) Yalnızca Vari Safe™ enjeksiyon iğneleri için: İğne 'iğne üzerinde' olarak nakliye edilmiştir. Bu, distal uçtaki iğnenin distal uçtaki yaya takılmasını önlemek için gereklidir. İğnenin distal ucundan uç koruyucuyu dikkatlice çıkarın. İğne kılıfını açın ve iğnenin uygun şekilde takıldığından emin olun. Luer kilit donanımını açın ve proksimal luer ileri-geri çalıştırarak iğnenin distal uçtan uygun şekilde ilerlediğini görsel olarak gözlemleyin. Geri dönüş yayı iğnenin geri çekilmesine yardımcı olur; ancak çekilmeyi her zaman gözle de kontrol edin.
   Not: Aleti esnetmeyin çünkü esnetme iğne takılma uzunluğunun değişmesine neden olabilir.
2. Dışarı pozisyonda iğneyi kilitlemek için proksimal luere, tutamak luerine ulaşıncaya kadar hafifçe basın ve ardından iki luer tam olarak birleşinceye kadar yavaşça saat yönünde çevirin.
3. Kabul edilen tıbbi metotları kullanarak iğne takımının havasını enjeksiyon maddesiyle çıkarın.
4. Endoskopa yerleştirmeden önce iğnenin tamamen çekildiğinden emin olun.
5. Onaylanan tıbbi teknikleri kullanarak istenilen sonuçlar elde edilinceye kadar uygun maddeyle enjeksiyona devam edin.
6. Bir enjeksiyon yerinden diğerine geçerken, mukozayı ve endoskopu travmadan/hasardan korumak için iğnenin kılıfına çekilmesi tavsiye edilir.
7. İğneyi endoskoptan çıkartırken, hastanın ve hekimin yaralanmasını engellemek ve endoskopu olası bir hasardan korumak için iğneyi kılıfına tamamen çekin.

Ürünün Atılması:
Kullanımdan sonra bu ürün potansiyel bir biyolojik tehlike oluşturabilir. Kabul edilmiş tıbbi uygulamalara ve ülkenizdeki ilgili yasa ve düzenlemelere uygun olarak kullanın ve atın.

Yayın Tarihi: Ekim 2008

Uyarı:
Bu talimatların yayın veya revizyon tarihi kullanıcının bilgisine sunulmuştur. Bu tarih ile ürün kullanımı arasında iki yıl geçmiş olması halinde, kullanıcı ek bir bilginin mevcut olup olmadığını belirlemek için US Endoscopy'yi aramalıdır.

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Bu ürün ve/veya kullanımı, ABD patent numarası 6.666.847 uyarınca koruma altındadır.

ABD'de Üretilmiştir.

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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본 1회용 연질 외장 주사기는 다양한 종류의 매체를 연질 내시경을 통해 주입하기 위한 것입니다.

경고 및 주의사항:

- 연질 내시경은 내시경술에 관한 적절한 훈련을 받은 숙달된 전문가에 의해서만 시술돼야 합니다. 모든 내시경은 사전에 그 기술, 금기 사항, 합병증, 위험성에 대하여 의학 정보를 참고하여 시술되어야 합니다. 내시경술 또는 금기 사항에 대한 참조 정보가 필요한 경우에는 US Endoscopy로 연락해 주십시오.
- 주사기의 운송 또는 취급상 손상이 발견된 경우에는 사용하지 마십시오.
- 본 주사기는 2.8mm 이상의 내시경 채널과 호환됩니다.
- Carr-Locke 주사기 전용: 카테터와 직선인 위치에서 주사기를 사용하지 마십시오. 주사기는 특정한 "사전 로드"가 된 상태에서 가공 및 제조됩니다. 이는 장치의 배열이 매우 구부러져 있을때 갈고리 끝의 바늘이 말단 허브에서 완전히 전진 또는 후진할 수 있도록 하기 위해 필요합니다. 카테터가 직선으로 위치한 상태에서 주사기가 작동한 경우, 이 "사전 로드"로 인해 바늘의 내부 카테터가 구부러져 적절한 주사를 할 수 없게 될 수도 있습니다. 주사기를 취급할 때는 항상 주사기의 끝 부분을 생각하면서 바늘이 장치 내부로 완전히 들어가 있는지 눈으로 확인하십시오.
- Vari-Safe™ 주사기 전용: 장치가 2회 이상 감긴 경우 내시경 외부에서 주사기를 작동시키거나 테스트하지 마십시오. 이렇게 하면 주사기가 말단 스프링의 근단부에 박힐 수 있기 때문입니다.
- 이 주사기는 1회용이며 재사용하여서는 안됩니다. 본 1회용 기기를 재처리, 재생, 재생산, 재소독 및/또는 재사용하는 기관, 의사 또는 제3자는 안전 및 효용성에 대해 전적인 책임을 져야 합니다.
- 본 IFU(사용 설명서)에 포함된 주사기는 Sodium Morrhuate, Sodium Tetradecylsulfate, Ethynolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline 및 Staining Media와 같은 의학용 재료 및 솔루션과 호환됩니다.
- 또한, Vari-Safe™ 주사기(제품 번호 00711818, 00711819 및 00711820)는 Triamcinolone(Kenalog)과 호환되는 것으로 확인되었습니다. 다른 물질과의 호환성은 확인되지 않았으므로 시도하지 마십시오.
- Carr-Locke and Articulator™ 주사기(제품 번호 00711811, 00711803, 00711804, 00711807 및 0071808)는 Pentax Model 90 series High Definition 위내시경과 호환되지 않지만, Carr-Locke 주사기(제품 번호 00711813)는 Pentax Model 90 시리즈 High Definition 위내시경과 호환됩니다.

금지 사항: 본 장치는 비협조적인 환자 및/또는 심각한 응고증 환자에게 사용해서는 안됩니다.

사용 지침:

8. (a) Articulator™ 및 Carr-Locke 주사기 전용: 주사기 말단부에서 보호 캡을 조심스럽게 제거합니다. 근단부 루어를 앞뒤로 움직여서 바늘이 장치의 말단부에서 정상적으로 나오는지 눈으로 확인합니다. 스프링이 장착된 핸들은 바늘이 후퇴할 때 도움이 됩니다. 그러나, 후퇴 상태를 항상 눈으로 확인하십시오. (주: 소장 내시경에 사용되는 제품 번호 00711808 버전은 이러한 스프링 장착 핸들 기능을 제공하지 않습니다).
   (b) 십이지장 내시경에서 Carr-Locke 주사기 사용: 십이지장 내시경을 사용하는 경우, 엘리베이터를 완전히 이동하기 전에, 후퇴 위치에 있을 때 말단 근단부의 스프링 내부에 있게 되는 주사기에 손상이 발생하지 않도록 주사기 의장이 소코프의 끝을 지나서 적절하게 돌출되어 있는지 확인하십시오.
   (c) Vari-Safe™_ 주사기 전용: 이 주사기는 "주사기가 돌출된" 위치에 있는 상태로 출하됩니다. 이것은 말단 스프링에 주사기 끝이 걸리지 못하도록 하기 위해 필요합니다. 주사기 말단부에서 보호 캡을 조심스럽게 제거합니다. 주사기의 의장을 풀고 주사기가 적절히 돌출되어 있는지 확인합니다. 루어 락 장치를 풀고 근단부 루어를 앞뒤로 움직여서 주사기가 말단부에서 적절하게 나오는지 눈으로 확인합니다. 리턴 스프링은 바늘이 후퇴할 때 도움이 됩니다. 그러나, 후퇴 상태를 항상 눈으로 확인하십시오.
   주: 본 기기를 늘이면 주사기의 주사 거리가 바뀔 수 있기 때문에 늘이면 안됩니다.
9. 주사기를 밖으로 나온 상태로 고정하려면, 근단부 루어를 핸들의 루어와 만날 때까지 천천히 누른 다음, 2개의 루어가 완전히 장착될 때까지 근단후 루어를 시계 방향으로 천천히 돌립니다.
10. 통용되는 의학적인 방법을 통해 주입 매체를 사용하여 주사기 어셈블리에서 공기를 소제합니다.
11. 본 기기를 내시경에 삽입하기 전에 주사기가 완전히 후퇴했는지 확인해야 합니다.
12. 원하는 결과를 얻을 때까지 승인된 의료 기술을 사용해서 적절한 매체의 주입을 계속합니다.
13. 하나의 주입 위치에서 다른 위치로 이동할 때, 점막과 내시경이 손상되지 않도록 주사기를 외피로 후퇴시켜서 넣도록 권장합니다.

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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14. 주사기를 내시경에서 제거할 때는 주사기를 외피로 후퇴해서 넣어서 환자나 의사가 상해를 입지 않고 내시경에 잠재적인 손상이 발생하지 않도록 보호하십시오.

제품 폐기:
한 번 사용된 제품은 생물학적으로 위험할 수 있습니다. 해당 의료 관례와 해당 지역, 주 및 연방 법 및 규정에 따라 제품을 취급하고 폐기하십시오.

발행일: 2006년10월

경고:
본 지침서의 발행일 및 개정일은 사용자에게 참조용으로 제공되는 것입니다. 본 날짜와 제품 사용일 사이에 2년 이상 차이가 있는 경우, 사용자는 US Endoscopy에 연락하여 추가 정보를 구할 수 있는지 확인해야 합니다.

Listening...and delivering solutions®, US Endoscopy listening...and delivering solutions 디자인, 그리고 ® 또는 ™으로 표시된 모든 상표는 미국 특허청 (U.S. Patent and Trademark Office)에 등록되어 있거나 US Endoscopy가 소유하고 있는 상표입니다.

본 제품 및/또는 그 사용은 미국 특허 번호 6,666,847로 보호됩니다.

제조원 : 미국

00730700 Rev. O

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 396

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Use By
Date limite d'utilisation
Zu verwenden bis
Usare entro
Fecha de caducidad
Validade
Udløbsdato
Uiterste gebruiksdatum
Son Kullanma Tarihi
사용 기한

Sterilized by Ethylene Oxide STERILE EO
Stérilisé par exposition à l'oxyde d'éthylène
Sterilisiert mit Ethylenoxid
Sterilizzato con ossido di etilene
Esterilizado con óxido de etileno
Esterilizado por óxido de etileno
Steriliseret med ethylenoxid
Gesteriliseerd met ethyleenoxide
Etilen Oksitle sterilize edilmiştir
산화 에틸렌으로 살균

Contents
Contenu
Inhalt
Contenuto
Contenido
Conteúdo
Indhold
Inhoud
İçindekiler
내용물

Non-Sterile NON-STERILE
Non stérile
Unsteril
Non Sterile
No estéril
Não estéril
Ikke-steril
Niet steriel
Steril değildir
비살균

Reference REF
Référence
Referenznummer
Referência
Referencia
Referência
Katalognr.
Referentie
Referans
참조

Single Use Only
Usage unique
Nur zum einmaligen Gebrauch
Solo per uso singolo
Un solo uso
Apenas para uma única utilização
Kun til engangsbrug.
Voor eenmalig gebruik
Tek kullanımlıktır
1회용으로만 사용

Lot LOT
Lot
Charge
Lotto
Lote
Lote
Lot-nummer
Partij
Lot
로트

Do Not Re-Sterilize
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
No reesterilizar
Não re-esterilizar
Må ikke resteriliseres
Niet opnieuw steriliseren
Yeniden sterilize etmeyin
재살균 금지

Date of Manufacture
Date de fabrication
Herstellungsdatum
Data di produzione
Fecha de fabricación
Data de fabrico
Fremstillingsdato
Productiedatum
İmalat Tarihi
제조일

Latex Free
Sans Latex
Latexfrei
Senza lattice
Sin látex
Sem látex
Latex-fri
Latexvrij
Lateks içermez
비라텍스 제품

Length
Longueur
Länge
Lunghezza
Longitud
Comprimento
Længde
Lengte
Uzunluk
길이

Read instructions prior to using this product
Lire les instructions avant d'utiliser le produit
Gebrauchsanweisung beachten
Leggere le istruzioni prima dell'uso
Leer las instrucciones antes de usar el producto
Ler as instruções antes de utilizar este produto
Læs brugsanvisningen, inden De begynder at anvende produktet
Lees de instructies voorafgaand aan het gebruik van dit product
Bu ürünü kullanmadan önce talimatları okuyun
본 제품의 사용 전에 설명서를 숙지하시오

00730700 Rev. C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 397

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Authorized Representative in the European Community
Représentant agréé dans la Communauté européenne
Autorisierter Repräsentant in der Europäischen Union
Rappresentante autorizzato nella Comunione Europea
Representante autorizado en la Comunidad Europea
Representante Autorizado na Comunidade Europeia
Repræsentant I EU
Erkende vertegenwoordiger in de Europese Gemeenschap
Avrupa Birliği Yetkili Temsilcisi
유럽 커뮤니티의 관련 대표

EC REP

For use with Olympus active cord
A utiliser avec le cordon actif Olympus
Zur Verwendung mit Olympus-Aktivlitze
Da usare con filo Olympus
Usar con el cable activo de Olympus
Para utilização com o fio activo Olympus
Anvendes med Olympus aktiv ledning
Voor gebruik met de actieve Olympus-kabel
Olympus aktif kablosuyla kullanılır
Olympus 액티브 코드에만 사용

Store at controlled room temperature
Conserver à température ambiante contrôlée
Lagerung bei kontrollierter Zimmertemperatur
Conservare a temperatura ambiente controllata
Almacenar a temperatura ambiente
Conservar a temperatura ambiente controlada
Opbevares ved stuetemperatur
Bewaren bij constante kamertemperatuur
Kontrol edilen oda sıcaklığında saklayın
일정 온도가 유지되는 실내에 보관 요망

15-25°C

For use with Microvasive active Cord
A utiliser avec le cordon actif Microvasive
Zur Verwendung mit Microvasive-Aktivlitze
Da usare con filo Microvasive
Usar con el cable activo de Microvasive
Para utilização com o fio activo Microvasive
Anvendes med Microvasive aktiv ledning
Voor gebruik met de actieve Microvasive -kabel
Microvasive aktif kablosuyla kullanılır
Microvasive 액티브 코드에만 사용

I.D.
D.I.
Innendurchmesser
D.I.
D.I.
D.I.
Indvendig diameter
Inwendige diameter
İç Çap
내경

O.D.
D. E.
Außendurchmesser
D.E.
D.E.
D.E.
Udvendig diameter
Uitwendige diameter
Dış Çap
외경

Do not use if packaging or product damage is evident. For sterile products only, contents are sterile if package is unopened and undamaged.

Ne pas utiliser si l'emballage ou le produit présente un dommage quelconque apparent. Pour les produits stériles uniquement, le contenu est stérile si l'emballage n'est ni ouvert, ni endommagé.

Wenn die Verpackung geöffnet oder beschädigt ist, darf das Produkt nicht verwendet werden. Für sterile Produkte gilt, dass der Inhalt steril ist, wenn die Verpackung ungeöffnet und unbeschädigt ist.

Non usare se il danno alla confezione o al prodotto è evidente. Solo per il prodotto sterile, il contenuto è sterile se la confezione è intatta e sigillata.

No use si el envaso o el producto está dañado. Sólo para productos estériles, el contenido se mantendrá estéril si el envase está cerrado e intacto.

Não utilizar se existirem danos evidentes na embalagem ou no produto. Apenas para produtos estéreis, o conteúdo é estéril se a embalagem não estiver aberta ou danificada.

Anvend ikke produktet, hvis pakken eller produktet er beskadiget. Kun sterile produkter: Indholdet er sterilt, hvis emballagen er uåbnet og uden skader.

Gebruik het instrument niet indien schade aan de verpakking of het product wordt vastgesteld. Voor steriele producten is de inhoud steriel als de verpakking ongeopend en onbeschadigd is..

Paket veya ürün hasar gördüyse kullanmayın. Yalnızca steril ürünler için, paket açılmamış veya hasar görmemiş olduğunda içindekiler steriltir.

포장 또는 제품이 파손된 경우에는 사용하지 마십시오. 멸균 용도로만 사용 가능하며, 제품의 포장이 개봉되기 않았거나 파손되지 않은 경우에 한하여 제품은 멸균 상태입니다.

Rx Only (U.S.A.)

Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.

Conformément à la législation américaine, cet appareil ne peut être vendu, distribué ou utilisé que par un médecin ou sur prescription médicale.

In den USA muss der Vertrieb oder die Verwendung dieses Produkts durch einen Arzt erfolgen bzw. ist verschreibungspflichtig.

Le leggi federali (degli Stati Uniti) vietano la vendita, la distribuzione o l'uso di questo prodotto senza prescrizione medica.

La ley Federal de los EE.UU. restringe la venta de este dispositivo a médicos o bajo prescripción facultative.

A lei federal (EUA) restringe este dispositivo a venda, distribuição e utilização por ou mediante prescrição de um médico.

Denne enhed må i henhold til amerikansk lovgivning kun sælges, distribueres og anvendes af en læge eller på lægeordination.

In de Verenigde Staten mag deze apparatuur volgens de federale wet uitsluitend door of op voorschrift van een arts worden gekocht, gedistribueerd en gebruikt.

ABD yasaları gereği bu cihaz yalnızca hekim tarafından ya da hekim siparişi üzerine satılabilir, dağıtılabilir veya kullanılabilir.

의료진에 의한 본 제품의 판매, 배급 또는 무단 사용은 미국 연방 법에 의거하여 금지되어 있습니다

00730700 Rev. O

Carr-Locke - injection needle Instructions For Use Page 14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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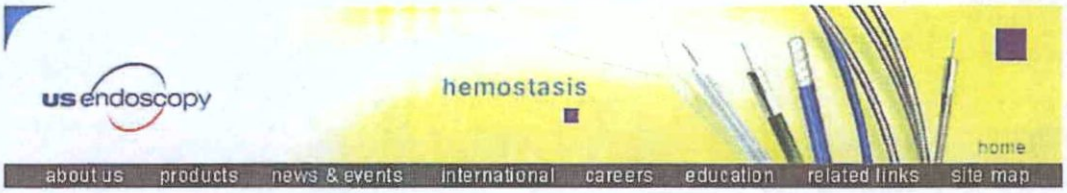

US Endoscopy | Hemostasis

US Endoscopy offers a line of sophisticated devices for injection therapy and hemostasis procedures. Our exclusive Carr-Locke Injection Needle is designed to operate in the most articulated conditions, including side-viewing duodenoscopes. Both the Carr-Locke and the ARTICULATOR™ Injection Needle feature a stainless steel sheath protecting against inadvertent needle perforation of the sheath.

Carr-Locke injection needle

Carr-Locke injection needle
Designed to achieve full deployment in extremely articulated conditions, the Carr-Locke needle is practical enough to use anytime and designed to work every time.

00711811
Carr-Locke
25 gauge injection needle, 5mm needle projection

>> *For more information*
>> *Publicity*

place order

Carr-Locke - injection needle Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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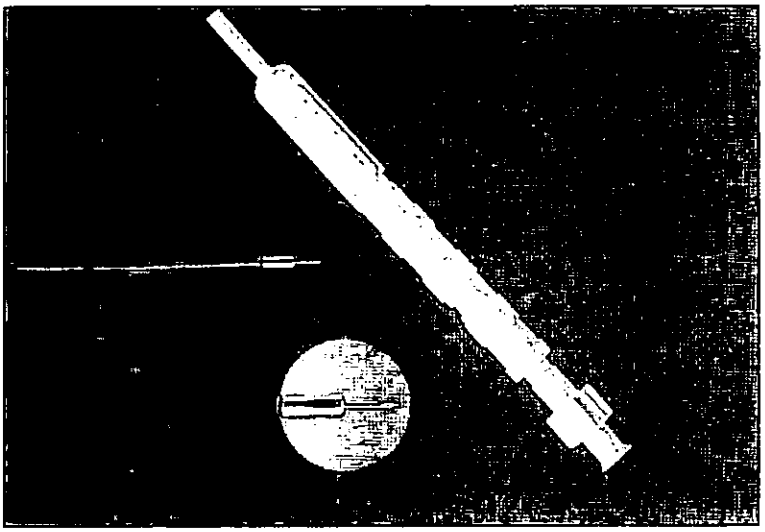
CARR-LOCKE Injection Needle

us endoscopy

The Carr-Locke Injection Needle is the next generation injection needle developed by US Endoscopy. While it is ideal for use in EGD and colonoscopy, it is the *only needle specifically designed for use through side-viewing duodenoscopes.* The Carr-Locke injection needle is designed to withstand the most tortuous of conditions, including activation of the elevator mechanism through a side-viewing duodenoscope. It features a high quality stainless steel sheath, and performs consistently and precisely to meet all your endoscopic needs. This premium device minimizes the kinking and needle perforations associated with plastic needles that can compromise patient safety, and often result in scope damage and use of additional products to finish the procedure (ultimately increasing time and device costs). The benefits of the Carr-Locke needle clearly outweigh the risks and costs associated with competitive injection needles, and make it the top choice of leading endoscopists worldwide.



US Patent No. 6,666,847

- **Stainless steel sheath**
  Minimizes problems associated with kinking and needle perforation
- **Smooth metal distal hub**
  Gentle on friable tissue, glides smoothly through biopsy channel and ideal for emergency tamponade situations
- **Radiopaque tip and shaft**
  Confirms positioning during ERCP procedures
- **Universal 230 cm length**
  Ideal for use in EGD, ERCP and colonoscopy procedures
- **Spring loaded handle**
  Allows rapid and reliable projection and retraction of needle during injection therapy
- **Disposable**
  Minimizes the risk of cross contamination

us endoscopy

5976 Heisley Road, Mantor, Ohio 44060
Phone (440) 639-4494 • Fax (440) 639-4495
Customer Service (800) 769-8226
Email: info@usendoscopy.com www.usendoscopy.com

Carr-Locke - injection needle Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

400

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CARR-LOCKE Injection Needle

us endoscopy

ORDERING INFORMATION
800-769-8226

Product Number	Description	Sheath Diameter (mm)	Sheath Length (cm)	Needle Projection (mm)	Units per Box
00711811	25 Gauge Injection Needle	2.5	230	5	5

The IDEAL injection needle for EGD, ERCP and Colonoscopy procedures.

Carr-Locke - injection needle Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

401

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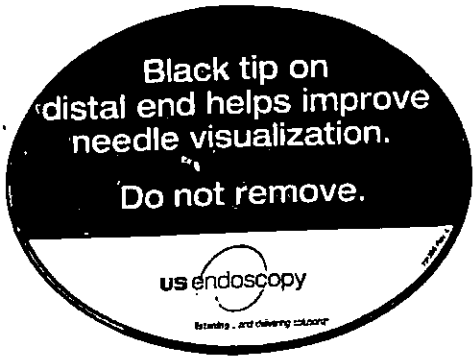

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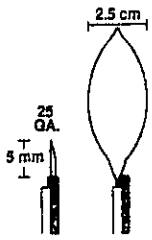
(800) 769-8226
Phone (440) 639-4494
Fax (440) 639-4495
Website: www.usendoscopy.com
E-Mail: info@usendoscopy.com



REF 00711086

230 cm
Ø 3.0 mm

LOT 764931

2010-11

2007-11

iSnare™ - Injection therapy & polypectomy system
iSnare™ - système de polypectomie et thérapie par injection
iSnare™ - Injektionstherapie und Polypektomiesystem
iSnare™ - sistema di terapia per iniezione e polipectomia
iSnare™ - tratamiento con inyección y sistema de polipectomía
iSnare™ - sistema de polipectomia e terapia de injecção
iSnare™ - Injektionsterapi- og polypektomisystem
iSnare™ - systeem voor injectietherapie en polypectomie
iSnare™ – enjeksiyon terapisi ve polipektomi sistemi

STERILE EO

15-23°C

LATEX

EC REP Richard J. Edmondson, Managing Director
Diagmed Lumley Close, Thirsk
North Yorkshire, England YO73TD
Phone - 44-1845-526660 Fax - 522199

CE 0086

Rx Only (U.S.A.)
MADE IN U.S.A.

us endoscopy REF 00711086 LOT 764931 2010-11

us endoscopy REF 00711086 LOT 764931 2010-11

us endoscopy REF 00711086 LOT 764931 2010-11

+H788007110860I

+SS900001111076493116

731174 Rev. www.usendoscopy.com 00731139 Rev. F 0049

iSnare™ - Injection therapy & polypectomy system Outer Packaging Pouch Labels

402

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

iSnare™ – injection therapy and polypectomy system

iSnare™ - système de polypectomie et thérapie par injection
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iSnare™ - tratamiento con inyección y sistema de polipectomia
iSnare™ - sistema de polipectomia e terapia de injecção
iSnare™ - injektionsterapi- og polypektomisystem
iSnare™ – systeem voor injectietherapie en polypectomie
iSnare™ – enjeksiyon terapisi ve polipektomi sistemi

Reorder No. 00711085 (23ga)
Reorder No. 00711086 (25ga)

INSTRUCTIONS FOR USE
Instructions d'utilisation
Gebrauchsanweisung
Istruzioni per l'uso
Instrucciones de uso
Instruções de Utilização
Brugsanvisning
Gebruiksaanwijzing
Kullanım talimatları

us endoscopy
listening...and delivering solutions
5976 Heisley Road
Mentor OH 44060
phone 440 / 639.4494
fax 440 / 639.4495
customer service 800 / 769.8226
www.usendoscopy.com

CE 0086

00731118 Rev. I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

STERILE EO RX Only (U.S.A.)

Intended Use:

- The iSnare™ - injection therapy and polypectomy system is a 3.0mm, dual lumen device providing both needle injection and monopolar electrocautery polypectomy snare capability within a single sheathed device. The device is indicated for the injection of media for sub-mucosal lift of polyps or other mucosal lesions within the gastrointestinal tract using direct visualization through a flexible front viewing endoscope prior to electrosurgical excision and for the infusion of fluid for clearing the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post polypectomy bleeding, and tattooing of sites for future surveillance or surgical purposes. The dual lumen device provides the user freedom from intra-procedural accessory device exchange during endoscopic gastrointestinal procedures. This device is compatible with Olympus® style active cords.

Warnings and Precautions:

- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to complications, hazards and techniques prior to the performance of any endoscopic procedure.
- The black distal tip of the needle sheath is designed to enhance needle performance. Do not tamper with the tip/do not attempt to remove.
- This device is not designed for use in a side viewing duodenoscope.
- Short strokes, 1"-1.5" (2.5cm – 3.8cm) in length, are recommended throughout device passage to avoid sheath kinking.
- Insertion and extraction forces during passage and withdrawal of the device through the endoscope's accessory channel will be greater in a 3.2 mm channel compared to the forces experienced in 3.7mm or larger channel diameter due to the 3.0mm diameter of the device's sheath.
- The user may additionally experience moderate resistance in device passage through the endoscope's channel based on intraprocedural scope configuration.
- The user may note a "heavier feel" when retracting the snare's handle/closing the snare loop around the desired tissue due to dual device/lumen presence within one sheath.
- Due to the large (3.0 mm) diameter of this device, the lid of the biopsy valve should be uncapped prior to channel passage to prevent excessive resistance that may cause the device's sheath to kink.
- If using a US Endoscopy BioShield® irrigator (product #00711133 or #0071137, biopsy valve with remote irrigation line) be aware that irrigation through the remote irrigation line should not be performed with the biopsy valve's lid open; doing so will cause fluid to leak from the valve.
- A thorough understanding of the technical principles of diathermic energy, as well as clinical applications and associated risks is necessary before using this device.
- To ensure patient safety, inspection of the active cord and the electrosurgical generator, as well as knowledge of proper settings and use must precede use of this device.
- Consult the electrosurgical generator manufacturer's instruction booklet for proper settings and use of the active cord and the generator.
- Care must be exercised when using electrocautery instruments to minimize the risk of patient injury. Safe and effective cautery is dependent on factors under the control of the user, as well as equipment design and its adequate inspection and maintenance.
- In order to ensure that the insulating properties of the device are not compromised, do not exceed the maximum rated recurring peak voltage stated for each high frequency mode **(see chart below)**.

High Frequency Mode	Maximum Rated Recurring Peak Voltage
Cut	1200 Volts
Coagulation Burst	2100 Volts
Coagulation Spray	5000 Volts

- Polypectomy should not be attempted unless proficiency in technique has been developed by the clinician.
- The correct method of polyp transection will depend upon the size of the polyp, as well as the type of polyp (e.g. pedunculated or sessile).
- Polypectomy procedures have been associated with complications such as burning or perforation of the intestinal wall.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

iSnare™ - Injection therapy & polypectomy system Instructions For Use Page 3

- **The snare should be fully retracted into the sheath during use of the injection needle to prevent inadvertent injury to the mucosa.**
- Endoscopic needle injection should not be attempted unless proficiency in technique has been developed by the clinician.
- The injection needle is compatible with the following medicinal substances and solutions: Sodium Morrhuate, Sodium Tetradecylsulfate, Ethynolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media. The compatibility of other substances has not been verified and therefore should not be attempted.
- Do not attempt to actuate this device with the sheath in a straightened position. The injection needle has been engineered and manufactured with a specific "preload" that is necessary to assure a full projection and full retraction of the needle from the barb stop when in tortuous configurations. If the device is actuated with the sheath in a straightened position, the "preload" may cause the needle's inner catheter to collapse and not allow for adequate injection.
- Do not stretch the device because stretching may alter needle projection length.
- When handling this device, always be aware of the device's distal tip and visually confirm that the needle is fully retracted into the sheath to minimize the risk of accidental injury to the patient, or clinician.
- **The needle should be fully retracted into the sheath during use of the snare to prevent inadvertent injury to the mucosa.**
- This disposable medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and or reuses this disposable medical device must bear full responsibility for its safety and effectiveness.

Contraindications:
Contraindications include those specific to any endoscopic procedure, use of electrocautery, uncooperative patients, and patients with coagulopathy. Consultation with appropriate medical personnel regarding use of this device in patients with a pacemaker or AICD device is the responsibility of the user.

The iSnare - injection therapy and polypectomy system is a dual handle device. Manipulation of the needle and/or snare is achieved using independent handle controls. The device is shipped in a prepackaged position with the polypectomy snare loop deployed and the injection needle retracted. The **diathermic finger ring handle** controls the snare loop. The **luer lock handle** controls the injection needle.

Pre-Use Instructions:
Prior to clinical use you should familiarize yourself with the device.

1. Read the "Instructions for Use" and review the diagrams.
2. Open the sterile package and visually inspect the device. If damage is evident, do not use the device.
3. The black distal tip of the needle sheath is designed to enhance needle performance. Do not tamper with the tip/do not attempt to remove.
4. Gently release and remove the banding straps that secure the device.
5. Uncoil the entire device. Do not attempt to manipulate the device handles until after the sheath has been carefully uncoiled and you are draping the device in a "U" shaped configuration, holding the proximal device end in one hand, and the distal device end in the opposite hand.
6. With the device in this position, retract the finger ring handle to withdraw the polypectomy snare loop back into its protective sheath.
7. To actuate the injection needle, advance and release the proximal luer lock handle and visually observe the needle projecting and retracting from the distal end of the device. The spring loaded handle assists in needle retraction, but visual observation of full needle retraction is always recommended in order to minimize the risk of damage to the endoscope or accidental injury to the patient or clinician.
8. **DO NOT STRETCH THE DEVICE BECAUSE STRETCHING MAY ALTER NEEDLE PROJECTION LENGTH.**
9. Due to the large (3.0 mm) diameter of this device, the lid of the biopsy valve should be uncapped prior to channel passage to prevent excessive resistance that may cause the device's sheath to kink.

iSnare™ - Injection therapy & polypectomy system Instructions For Use Page 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Directions for Use

1. Following recommended techniques, perform EGD or Colonoscopy.
2. **To prepare the injection needle for use**, the needle should be locked in the out position by:
   - Gently pressing the proximal luer until it meets the handle luer and then slowly twist clockwise until the two luers are fully engaged (see Fig. 1; Fig. 1A shows distal tip with needle deployed).
   - The needle assembly should then be purged of air with injection media.
   - The needle should be unlocked/ retracted into its sheath by gently twisting the proximal luer counter clockwise until the two luers are fully disengaged (see Fig. 2; Fig. 2A shows distal tip with needle retracted).
3. Always ensure that the needle is fully retracted prior to inserting the device into the endoscope.
4. **To prepare the polypectomy snare for use** – securely attach the Olympus® style active cord to the device's diathermic handle. The electrosurgical generator should be set to the proper settings that allow transection of the polyp with controlled hemostasis. Consult the electrosurgical generator manufacturer's instruction booklet for proper use of the generator, proper settings, use of the active cord, and the proper application and position of the patient return electrode.
5. Due to the large (3.0 mm) diameter of this device, uncap the lid of the biopsy valve prior to passage through the endoscope's accessory channel to prevent excessive resistance that may cause the device's sheath to kink (see Fig. 3).
6. After endoscopic identification of the desired injection site, pass the device through the accessory channel of the endoscope and proceed with injection of appropriate media using approved medical techniques until desired results are accomplished.
7. The needle should then be released and fully retracted back into its sheath. Visual observation of full needle retraction is always recommended in order to minimize the risk of damage to the endoscope or accidental injury to the patient or clinician.
8. Open the snare loop by advancing the finger ring handle until it stops. Confirm that the snare loop is fully open via endoscopic observation (see Fig. 4).
9. Position the snare loop and transect the polyp using proper surgical technique.
10. Once the polyp has been satisfactorily transected, the polyp fragment (s) should be removed and the specimen (s) prepared according to standard technique for histologic evaluation.
11. When removing the device from the endoscope, ensure that the snare loop as well as the needle is fully retracted into the device sheath in order to minimize the risk of damage to the device and the endoscope, or injury to the patient and the clinician (see Fig.5).

Product Disposal:
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: July 2007

Warning:
An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

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Olympus® is a registered trademark of Olympus Optical Co., Ltd.

Made in the U.S.A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 406

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FIG. 1 ADVANCE AND TWIST LUER LOCK CLOCKWISE TO DEPLOY AND LOCK NEEDLE IN THE OUT POSITION

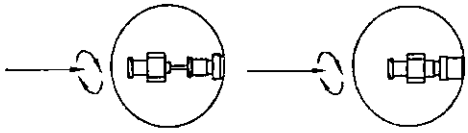


FIG. 1A BLACK DISTAL TIP NEEDLE DEPLOYED

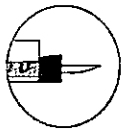


FIG. 2 TWIST LUER LOCK COUNTERCLOCKWISE TO UNLOCK AND RETRACT NEEDLE

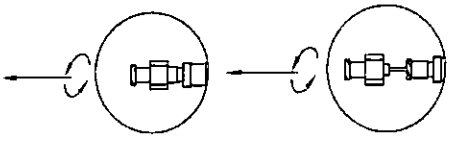


FIG. 2A BLACK DISTAL TIP NEEDLE RETRACTED

FIG. 3 UNCAP / OPEN THE LID OF THE BIOPSY VALVE FOR DEVICE PASSAGE

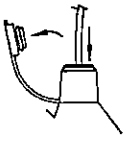


FIG. 4

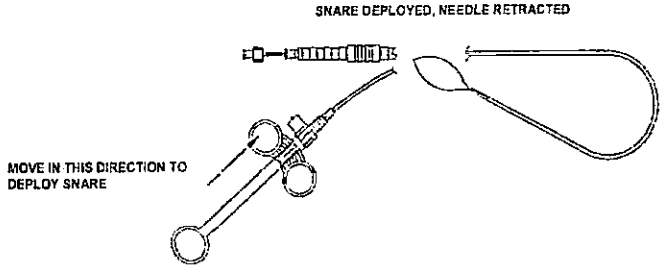
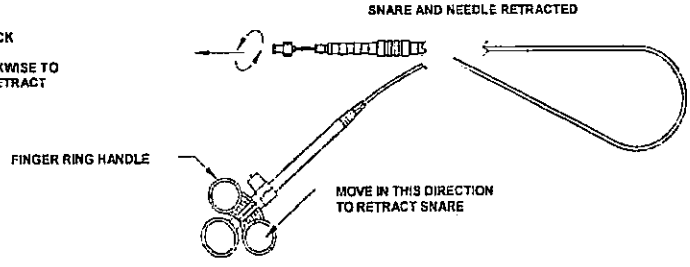


FIG. 5 TWIST LUER LOCK HANDLE COUNTERCLOCKWISE TO UNLOCK AND RETRACT NEEDLE



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 407

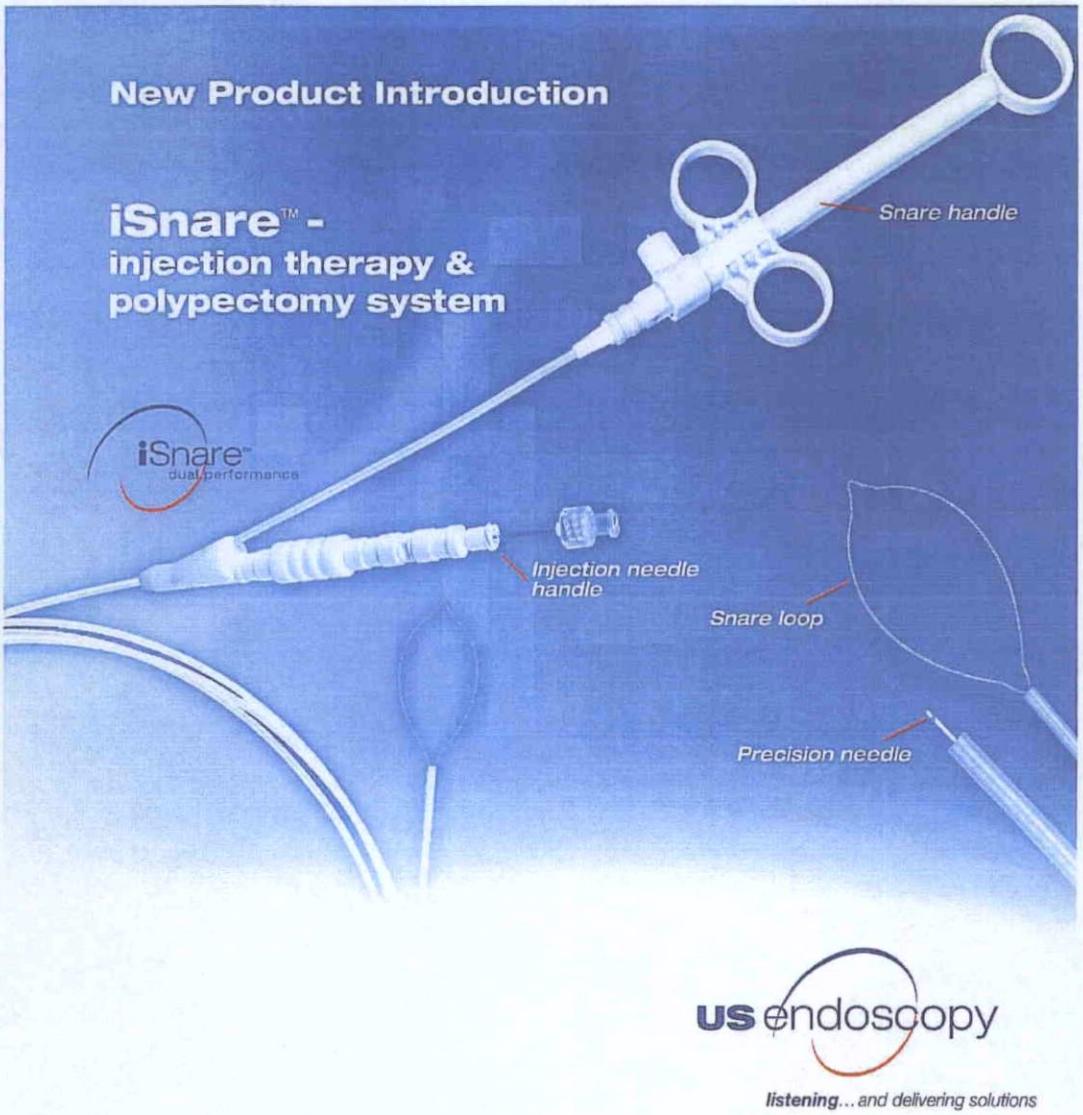
Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Explanation of symbols used on Labels and Instructions for Use

Use By		Sterilized by Ethylene Oxide	STERILE EO
Contents		Non-Sterile	NON-STERILE
Reference	REF	Single Use Only	2
Lot	LOT	Do Not Re-Sterilize	2 Sterile
Date of Manufacture		Latex Free	LATEX
Length	⊢ ⊣	Read instructions prior to using this product	⚠
Authorized Representative in the European Community	EC REP	For use with Olympus® active cord	
Store at controlled room temperature	15-25°C	For use with Microvasive® active Cord	
I.D.		O.D.	∅
Do not use if packaging or product damage is evident. For sterile products only, contents are sterile if package is unopened and undamaged.			
Rx Only (U.S.A.) Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.



iSnare™ - Injection therapy & polypectomy system Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

409

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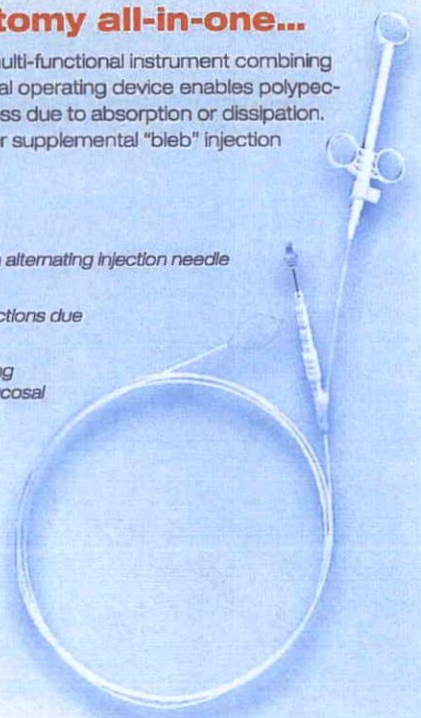
Injection therapy and polypectomy all-in-one...

US Endoscopy is proud to introduce the iSnare™ – a unique, multi-functional instrument combining injection needle and polypectomy snare technologies. This dual operating device enables polypectomy immediately following saline injection, minimizing "bleb" loss due to absorption or dissipation. The iSnare also allows for direct hemostasis injection therapy or supplemental "bleb" injection during large or difficult saline assisted polypectomy cases.



The iSnare's unique design...

- *Enables **multi-functional therapy with one device** featuring an alternating injection needle and snare function operated by a single, multi-faceted handle*
- *Facilitates **instantaneous injection** for responsive, repeated injections due to absorption, dissipation and bleeding*
- *Offers **added efficiencies for a variety of procedures** requiring subsequent injection and snare treatment such as endoscopic mucosal resection (EMR), saline assisted polypectomy and adherent blood clot removal*
  - ***Minimizes wasted procedural time spent exchanging devices** - inject or snare at anytime **throughout the procedure** without withdrawing the device*
  - *Features a luer lock handle for **consistent needle projection and retraction***
  - *Incorporates a **familiar handle configuration** for easy operation of the snare function, ensuring comfort and ease of control*

The iSnare can be utilized for all of the following endoscopic needs: *cleansing, applying dye or stain during chromoendoscopy, SAP (saline assisted polypectomy), EMR (endoscopic mucosal resection), hemostatic injection and adherent clot removal, injection therapy, tattooing pre- or post-polypectomy, and any other procedure requiring injection therapy and snare transection techniques.*

For more information on the iSnare, contact US Endoscopy today.

product number	description	needle gauge	needle length	snare size	sheath diameter	sheath length	active cord connector	units/ box
00711086	iSnare	25	5mm	2.5 x 4.0cm	3.0mm	230cm	Olympus®	5 units/box

us endoscopy
listening ... and delivering solutions
5976 Heisley Road
Mentor OH 44060
phone 440 / 639.4494
fax 440 / 639.4495
customer service 800 / 789.8226
www.usendoscopy.com

iSnare™ is a trademark of US Endoscopy patent pending
Olympus® is a registered trademark of Olympus Optical, Inc.

706205 Rev B

iSnare™ - Injection therapy & polypectomy system Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

PROPOSED LABELING AND MARKETING STATEMENTS

List of Proposed Labels and Labeling as well as Marketing Statements

Description	Page Number
Labels	
ERBELIFT™ Hand Pump	
Outer Packaging Carton Label	V-30
ERBELIFT™ Flexible Probe	
Outer Packaging Pouch Label	V-30
Outer Packaging Carton Label	V-31
Outer Packaging Case Label	V-31
Labeling	
Instructions On Use	V-32 to V-33
Marketing Statements	
Marketing Statements/Claims	V-34 to V-35

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

REF CAT. **7912-1001** LOT NSXXXX-XXX

ERBELIFT™ Hand Pump

Reusable

CONSULT INSTRUCTIONS FOR USE

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

ERBE

Distributed By:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067

QUANTITY:
One (1)

LIT/5209/00 01/09

ERBELIFT™ Hand Pump Outer Packaging Carton Label

REF CAT. **7912-1002**

STERILE EO STERILIZED USING ETHYLENE OXIDE

ERBELIFT™ Flexible Probe,
O.D. 1.3 mm x L. 2.6m

SINGLE USE ONLY DO NOT REUSE DO NOT RESTERILIZE

LOT STXXXX-XXX

CONSULT INSTRUCTIONS FOR USE

EXPIRATION DATE XXXX-XX

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Sterility not guaranteed if package has been opened or damaged.

ERBE

Distributed By:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067

QUANTITY:
One (1)

LIT/5205/00 01/09

ERBE LOT STXXXX-XXX REF 7912-1002

ERBE LOT STXXXX-XXX REF 7912-1002

ERBE LOT STXXXX-XXX REF 7912-1002

ERBE LOT STXXXX-XXX REF 7912-1002

ERBELIFT Flexible Probe Outer Packaging Pouch Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

112

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

REF CAT. **7912-1002**

STERILE EO STERILIZED USING ETHYLENE OXIDE

ERBELIFT™ Flexible Probe,
O.D. 1.3 mm x L. 2.6m

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

LOT STXXXX-XXX

CONSULT INSTRUCTIONS FOR USE

EXPIRATION DATE XXXX-XX

ERBE

Distributed By:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Sterility not guaranteed if package has been opened or damaged.

5

QUANTITY:
Five (5)

LIT/5206/00 01/09

ERBELIFT™ Flexible Probe Outer Packaging Carton Label

REF CAT. **7912-1002**

STERILE EO STERILIZED USING ETHYLENE OXIDE

ERBELIFT™ Flexible Probe,
O.D. 1.3 mm x L. 2.6m

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

LOT STXXXX-XXX

CONSULT INSTRUCTIONS FOR USE

EXPIRATION DATE XXXX-XX

ERBE

Distributed By:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Sterility not guaranteed if package has been opened or damaged.

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QUANTITY:
Eighty (80)

LIT/5207/00 02/09

ERBELIFT Flexible Probe Outer Packaging Case Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

ERBELIFT™ Hand Pump and Flexible Probe — *Instruction For Use*

Caution! Federal law restricts this device to sale by or on the order of a physician.

Hand Pump, No. 7912-1001
Reusable Pump that is loaded with a sterile normal saline-filled syringe which connects to a Flexible Probe (Note: The Hand Pump can be used for 100 procedures).

Flexible Probe, No. 7912-1002
Single use Probe that connects to a sterile normal saline-filled syringe that is loaded into a Hand Pump.

Accessories Needed but Not Provided
Normal Sterile Saline
Syringe Type: DeRoyal Medical Products, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings) Control Syringe, Product Number 77-712391. An 8 ml size can also be used (Product Number 77-400391).

Note: The working channel of the endoscope must have a diameter larger than 1.5 mm.

Safety Instructions

WARNINGS

The products may only be used by medical personnel who have been trained per these instructions.

Hand Pump
Clean/Disinfect the Hand Pump prior to using the device the first time and before every subsequent use. Before each use, check that the product is intact. Verify that there are no signs of physical damage. If damaged, do not use this product. Protect this product from any form of mechanical damage.

Flexible Probe
Sterility is not guaranteed if the package has been opened or damaged. Discard if the package is damaged. An expiration date is printed on the packaging of the device. Do not use any product beyond its expiration date. When using the device clinically (within a patient), do not puncture the mucosa with the Probe's tip. Dispose of the product after use. The device is only intended to be used once. Do not re-sterilize.

Byrne Medical, Inc. expressly warns against modifying the products. Any modification exempts Byrne Medical, Inc. from any and all liability.

Intended use

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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How to use

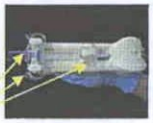
1. Prior to use, clean and disinfect the Hand Pump by wiping with water and a hospital grade disinfectant. Follow the manufacturer's instructions for using the disinfectant.
2. Pull back the plunger of the Hand Pump.

3. Using accepted medical methods, open the packaging of the syringe and fill it with sterile normal saline.
4. Use aseptic techniques to open the pouch of the Flexible Probe and remove the Probe from its protective sheath (i.e. hoop).

Note: Ensure that the Probe's integrity is not compromised throughout its use.

5. Connect the Probe's hub luer to the syringe. Ensure that the connection is secure.

6. Load the syringe into the barrel of the Hand Pump at the three (3) connection points.



Connection Points

7. Using accepted medical methods, squeeze the trigger of the Hand Pump to purge the attached Flexible Probe of air with the normal saline (i.e. purge the Probe.).
8. When needed, place the distal end of the Flexible Probe down the working channel of the endoscope. Under direct visualization, place the Probe's tip against the target tissue where a submucosal lift is desired (Note: Do not puncture the mucosa with the Probe's tip.).
9. To create the desired lift, squeeze the handle in a controlled manner while viewing the cushion formation. Create other lifts as desired.
10. After use, remove the Flexible Probe from the endoscope. The Probe may be a potential biohazard. Therefore, handle and dispose of the Probe in accordance with accepted medical practices as well as with local, state and federal regulations. Finally, clean and disinfect the Hand Pump by wiping with water and a hospital grade disinfectant. Follow the manufacturer's instructions for using the disinfectant.

ERBE USA Incorporated Surgical Systems

Distributor:
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Phone No.: 770-955-4400 or 800-778-3723
Fax No.: 770-955-2577

Manufacturer: Byrne Medical; 3150 Pollok Drive; Conroe, TX 77303

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Marketing Statements/Claims

- The ERBELIFT™ Hand Pump and Flexible Probe produces submucosal elevations as traditional needle-injection systems.
- Easy to use devices.
- An easier and less demanding method of generating force to drive the fluid into the submucosa.
- Needle-less submucosal elevation.
- No mechanical trauma of using a needle, need to find the submucosal plane with a needle, or perforation with a needle.
- Hand Pump
  - Ergonomic Pistol Grip Design:
    - Supports natural wrist posture / position.
    - Intuitive hand placement.
    - Ambidextrous operation.
    - Form and dimensions to accommodate both the female or male user's anthropometric hand specifications.
    - Center of gravity passes through the grip of the handle of the grasping hand, minimizing fatigue.
    - Curved handle design to avoid compressive forces against the soft tissue of the hand[1].
    - Non-slip materials support the effective grip between the wet, gloved hands and the pump.
  - Comfortable, One Hand Activation:
    - Easy operation due to less gripping force compared to an in-line tool handle or motion (e.g. force applied to syringe connected to an injection needle)[2].
    - The separation length of the trigger to the handle base allows either a male for female user to wrap up to four fingers around the trigger and maximize their grip pull strength[3].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

- The length and shape of the trigger allows either a male for female user to comfortably wrap up to four fingers around the trigger to minimize discomfort during multiple activations.
- The user can easily control when to immediately stop and / or to reinitiate the flow due to the mechanical drive mechanism per pull / activation.

  - Easy to monitor fluid volume from the mounted control syringe since each activation (trigger pull) delivers a quantified output.

- Flexible Probe
  - Connecting hub with standard luer lock that is winged which allows easy connection to the syringe, especially with wet gloves.
  - Small outer diameter tubing which is compatibility with a large range of flexible endoscope working channel sizes.
  - Smooth but sturdy tubing allows for easy insertion in a scope as well as removal from a scope.
  - In larger working channel scopes, the Probe maybe able to be passed down alongside another instrument.
  - There is no needle to cause damage to the channel of the scope.

[1] http://www.advancedergonomics.com/product/tools.htm

[2] http://www.agrabilityproject.org/assistivetech/tips/handtools.cfm

[3] http://www.ccohs.ca/oshanswers/ergonomics/handtools/tooldesign.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-26-2012

COVER SHEET MEMORANDUM

From: Reviewer Name M J Cornelius

Subject: 510(k) Number K092090/S

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

.ev. 7/2/07

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
anotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
876.1500	II	FBK

(*If unclassified, see 510(k) Staff)

Additional Product Codes: KZE

Review: _____ (Branch Chief) WDB (Branch Code) 11/30/09 (Date)

Final Review: _____ (Division Director) 11/30/09 (Date)

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Date: November 23, 2009
Office: ODE
To: The Record
Division/Branch: DRARD/ULDB
From: M. J. Cornelius
510(k) Holder: Byrne Medical, Inc.
Device Name: K092090 ERBELIFT Hand Pump and Flexible Probe
Common Name: Flushing Pump
Contact: Daniel W. Lehtonen, Sr. Staff Engineer - Medical Devices
Email: dan.lehtonen@intertek.com **Phone:** 937-313-7454

I **Purpose and Submission Summary:** Byrne Medical, Inc. would like to introduce the ERBELIFT Hand Pump and Flexible Probe into interstate commerce. This needleless method of injecting fluids is a new device for Byrne Medical, Inc.

II **Indications for Use:** The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in to the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

III **Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form #3654	✓		
Clinical Trials Form			✓

IV **Device Description:**

- **Hand Pump** is a gun-shaped component with a handle and a barrel (slot for mounting a syringe) used for the delivery of pressurized sterile normal saline. It is reusable and delivers approximately 0.75 ml of normal saline per squeeze of the handle. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of **145 to 650 psi, which** correlates to flow rates of **17 to 38 ml/minute**. The pressure and flow rate depend upon the number of times the handle is squeezed.
- **The Flexible Probe** consists of a handle with a standard Luer lock connection hub and 260 cm catheter (tubing). Its distal tip is tapered to approximately 0.005" that delivers a jet stream of 120

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μrn. It is provided as sterile and labeled for single use. The probe is 260 cm in length with an outer diameter of 1.3 mm and an inner diameter of 0.120 mm.

- **A control syringe** (previously cleared under K920135 is intended to be used as an accessory with the proposed device; however it is not provided with the device.

The proposed system employs a needle-free mechanism that does not puncture the tissue. Instead, the combination of the force of the saline applied via the Hand Pump/ syringe combination and the placement of the flexible probe enables the saline to be inducted through the tissue and disperse into the submucosal layer. This process allows the user to achieve their desired polyp lift. The pressure and flow rate of saline delivery depend upon the speed with which the Hand Pump handle is squeezed (the more times the users squeezes the handle over a given time the higher the pressure and flow rate). However, each squeeze of the handle delivers 0.75 ml (approx.) saline, thus the user has control of how much saline is being delivered.

	Yes	No	N/A
Is the device life supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile? **Flexible Probe**	✓		
Is the device reusable (not reprocessed single use)? **Pump**	✓		
Are "cleaning" instructions included for the end user?	✓		

IV. Device Comparison:

	Byrne Medical EndoGator™	United States Endoscopy Injection Needle K924102	United States Endoscopy Injection Needle/Snare K040961
Indications for use	The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal polyps or other mucosal lesions using direct visualization through a flexible endoscope	The U.S. Endoscopy needle is indicated for use with flexible gastroscopes, colonoscopes, sigmoidoscopes, duodenoscopes, choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of fluids or tissue and for injection of medications or dyes into tissue.	The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization through flexible through flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes. The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization through flexible through flexible endoscope,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

			prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.
Physical Characteristics			
Hand Pump	A Gun Shaped Device with a Handle and a Slot for mounting a syringe	Not Applicable	Not Applicable
Needle or Probe	Handle with a Standard Luer Lock Connection Hub and Catheter (Tubing)	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle	Handle with a Standard Luer Lock Connection Hub Catheter (Tubing) with Extension Needle and Snare
Working Length	260 cm	230 cm	230 cm
Outer Diameter	1.3 mm	2.5 mm	3.0 mm
Force/Flow rate	145-160 psi/17-38 ml/minute	Unknown-Dependent on force applied needle and on pump of syringe	Unknown-Dependent on force applied needle and on pump of syringe

The predicates (K040961and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. For the proposed device with a needle-free system, the Hand Pump is included to provide the force to the control syringe for inducing the pressurized fluid into the submucosa to achieve desired lift. This technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 IJm in diameter (compared to 810 IJm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue

VI Labeling:

Draft labeling has been provided which includes detailed instructions for use, relevant warnings and precautions and an appropriate prescription statement as required by CFR 21.807.87 (e). Reprocessing instructions for the pump are included.

VII Sterilization/Shelf Life/Reuse

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	ETO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EO <20 mg/device ECH <12 mg/device	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is	ANSI/AAMI/ISO 11135-1	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))		
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	Probe packaged in protective sheath with Tyvek pouch	
6. Shelf Life (ASTM F1980-2007)	Accelerated aging 3 years	

VIII **Materials:** (Patient contacting)

- Flexible Probe shaft and tip: Polyetheretherketone (PEEK) and Nylon (Medical grade inks used to imprint logos on the Probe)

IX **Biocompatibility:** **Tab 4 Exhibit 3.1**

Results of biocompatibility testing as described in the FDA Guidance Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices *http:l/www.fda.eov/cdrh/e951.html* in compliance with International Standard ISO-I0993, 'Biological Evaluation of Medical Devices Part-I: Evaluation and Testing, Part-5 Tests for in vitro cytology; and Part-l0 Tests for Irritation (Second Edition)

X **Software:** N/A

XI **Electromagnetic Compatibility and Electrical, and Thermal Safety** N/A

XII **Performance Testing – Bench** N/A

XI. **Performance Testing – Animal**

Purpose: To determine whether a hand-pump needle-free elevation system will affect procedure time and generate tissue elevation without complication when compared to a needle system.

A. **Ex-Vivo Study:** 10 tissue elevations were performed by 5 endoscopists (2 master clinicians, 2 trainees and 1 novice), using 10 ml of blue-colored normal saline. 5 elevations were performed with the proposed needle-free induction system and 5 with a predicate needle injection system in a porcine stomach model. Each endoscopist was randomly assigned an individual, freshly harvested stomach from a Yorkshire pig (> 25 kg) and the following parameters were measured:

Test	Result: Erbelift vs U.S. Endoscopy Injection Needle K924102
Flow rate (mils),	No statistical difference
Height of elevation (mm)	No statistical difference
Procedure duration(s)	Erbelift; 19 minutes; Predicate 28 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Perforation rate	None
Accuracy of elevation placement	Comparatively accurate
Diameter of bleb (2 axis in mm)	40.2±10.3 mm; Predicate; 33.0±11.3

B. **In Vivo Study:** 20 tissue elevations were performed by 3 endoscopists (master clinicians, 1 trainee and 1 novice), using 1.5ml of blue-colored normal saline.

- Flow rate: No statistical difference
- Perforation at Maximum force

Conclusion: Results of testing demonstrate that the device is as safe and effective as the predicate.

XII Performance Testing – Clinical N/A

XIII Postmarket Surveillance Information: Not relevant

XIV Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

3. Describe the new technological characteristics: Needless injectors depend on the force applied and contact site and are not new technology. However, a needless injection into the gastric mucosa is a new method of injection. The predicates (K040961 and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. The proposed device with a needle-free system and Hand Pump is also designed to lift polyps or other mucosal lesions.
The differences technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 μm in diameter (compared to 810 μm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

4. Explain how new characteristics could or could not affect safety or effectiveness: Results of in-vivo and ex-vivo demonstrate that safety and effectiveness are not compromised with this technology

8. Explain how the performance data demonstrates that the device is or is not equivalent: Based on a comparison of performance The Erbelift Hand Pump and flexible tubing are equivalent to the predicate devices identified.

XII. **Deficiencies:** See Memo dated July 29 with responses dated September 28, 2009 (Attached)

XIII. Contact History: Telephone Hold July 29, 2008

XIV. Recommendation

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II,
Product Code: FBK endoscopic injection needle, gastroenterology-urology
KZE injector, fluid, non-electrically powered (CFR 880.5430)

Mary J Cornelius
Reviewer

11/23/09
Date

Branch Chief

Date

12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DEPARTMENT of Health and Human Services

Food and Drug Administration
Center for Devices and Radiological Health

Memorandum

Date: July 29, 2009 and November 23, 2009
From: M. J. Cornelius
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe
Contact: Daniel W. Lehtonen **Phone:** 937-313-7454 OH **FAX:** 330-405-5518
Email: dan.lehtonen@intertek.com and jay.kogoma@intertek.com
To: Record After reviewing the third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, addition information is required as follows:.

1. Your review memo references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.

Response: Data provided and reviewed in Memo to the Record dated 11/23/09

2. Your review memo references the maximum pressure delivered by the subject device as 650 psi. However, your memo does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids, however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information:
   A. how the determination of less trauma was ascertained;
   B. amount of pressure generated by the ERBELIFT Hand Pump compared to the amount of pressure generated by hand on the syringe;
   C. provide upper limit of pressure which results in perforation; and
   D. method used to ensure that pressure generated does not exceed 650 psi maximum listed.

Response: Data provided and reviewed in Memo to the Record dated 11/23/09

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Mary Jo Cornelius

Subject: 510(k) Number K092090

To: The Record

Please list CTS decision code ~~AI~~ 1H

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Rev. 7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: 7/28/09

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

DEPARTMENT of Health and Human Services

Food and Drug Administration
Center for Devices and Radiological Health

Memorandum

Date: July 29, 2009
From: M. J. Cornelius
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe

Contact: Daniel W. Lehtonen **Phone:** 937-313-7454 OH **FAX:** 330-405-5518
Email: dan.lehtonen@intertek.com and jay.kogoma@intertek.com
To: Record

Intended use The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in to the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Device Description:

Hand Pump is a gun-shaped component with a handle and a barrel (slot for mounting a syringe) used for the delivery of pressurized sterile normal saline. It is reusable and delivers approximately 0.75 ml of normal saline per squeeze of the handle. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of **145 to 650 psi, which** correlates to flow rates of **17 to 38 ml/minute**. The pressure and flow rate depend upon the number of times the handle is squeezed.

The Flexible Probe consists of a handle with a standard Luer lock connection hub and 260 cm catheter (tubing). Its distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 µm. It is provided as sterile and labeled for single use. The probe is 260 cm in length with an outer diameter of 1.3 mm and an inner diameter of 0.120 mm.

The ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe (previously cleared under K920135 is intended to be used as an accessory with the proposed device; however it is not provided with the device.

K920135 Angiographic injector and syringe. DXT 870.1650 MedRoyal Angiographic Control Syringe and Palm Plate/Thumb Ring

The four proposed syringes are as listed below.
10cc Syringe with a Fixed Male Luer Lock and a Thumb Grip
10cc Syringe with a Fixed Male Luer Lock and a Palm Pad
10cc Syringe with a Rotating Male Luer Lock and a Thumb Grip
10cc Syringe with a Rotating Male Luer Lock and a Palm Pad

Substantial equivalence is claimed to:
K924102 FBK endoscopic injection needle, gastroenterology-urology 876.1500

Intended Use: The U.S. Endoscopy needle is indicated for use with flexible gastroscopes, colonoscopes, sigmoidoscopes, duodenoscopes choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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fluids or tissue and for injection of medications or dyes into the tissue.

K040961 FBK endoscopic injection needle, gastroenterology-urology 876.1500 and **FDI** Endoscopic electrosurgical unit and accessories 876.1500
The Endoscopic Injection Needle/Snare is a dual channel device combines two devices into one combination device, which performs two separate functions electrosurgical snare and injection needle.

Intended Use: The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through a flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view. applying dye spray, clot removal, injection of hemostatic agents to control postpolypectomy bleeding, and tattooing of sites for future surgical purposes.

Animal study:
Ten (10) elevations were performed with the proposed needle-free elevation system and 1o with predicate needle injection system in a live porcine model (a >25 kg Yorkshire pig). The following data points were measured:

- Flow rate (ml/s)
- The volume (10 ml) of saline for the in-vivo **studies does not reflect the actual amount to be administered for the device use. This volume is selected solely to demonstrate the comparison between the proposed device and the predicate.**

Parameters Tested	Proposed ERBELIFT (Needle Less injection	K924102 Carr Locke (Injection Needle	Results
Ex- Vivo Study			
Mucosal lift (independent of endoscopist skill[1]	Accomplished in 100% 10 cases	Accomplished in 92%	Mucosal lift was greater with the ERBELIFT
Perforations	None	None	
Ease of use[2]	in 92% cases	in 64% cases	
Accuracy	< 3mm in 100% cases	3mm in 76% cases	proposed device reported comparatively accurate[3]
Height of elevation	15.27 ±4.99 mm	15.84 ±5.5 mm	no statistical difference
Flow rate	061 ± 009 mils	053 ± 023 mils	no statistical difference
Total procedure time	19.36 ±3.35 sec.	28.2' ± 8.85 sec.	ERBELIFT resulted in reduced procedure time
Maximum lift diameter	40.18±10.26 mm	33.03 ± 11.31 mm	Mucosal lift was greater with the ERBELIFT

1. Endoscopist skill level: 5 endoscopists (2 master clinicians, 2 trainees, 1 novice)
2. Ease of use is defined as simple, fair, unacceptable. This is a subjective determination and therefore of little use

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In vivo studies performed by 3 endoscopists, (1 master clinician, 1 trainee, 1 novice)

In- Vivo Study			
Flow rate	0.39 ± o.o5 mils	0.36 ± o.o7 mils	no statistical difference
Perforations (at maximum force)[3]	None	None	

3. Perforation risk at maximum force. Defined as the maximum pull/activation force applied to the trigger of the hand pump by the user who is deliberately ignoring the visual tissue effect - essentially simulating negligent use of the product.

Conclusion: The predicates (K040961 and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. The proposed device with a needle-free system and Hand Pump is also designed to lift polyps or other mucosal lesions. The differences technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

1. Your review memo identifies predicate devices within the KZE (Nonelectrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.*

*** NOTE: Questions 1 was not sent to the contact pending a decision concerning the correct product code**

After reviewing your third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, it appears that addition information is required. The following information is necessary to continue the review of this 510(k).

1. Your review memo references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that

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additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.

2. Your review memo references the maximum pressure delivered by the subject device as 650 psi. However, your memo does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids, however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information:

   A. how the determination of less trauma was ascertained;

   B. amount of pressure generated by the ERBELIFT Hand Pump compared to the amount of pressure generated by hand on the syringe;

   C. provide upper limit of pressure which results in perforation; and

   D. method used to ensure that pressure generated does not exceed 650 psi maximum listed.

This submission has been placed on telephone hold (see attached email)

M J Cornelius 07/29/09

Reviewer Date

7/29/09

Branch Chief Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 131

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(;lius, Mary Jo

From: Cornelius, Mary Jo
Sent: Wednesday, July 29, 2009 11:56 AM
To: 'jay.kogoma@intertec.com'; 'dan.lehtonen@intertek.com'
Cc: Janda, Michel D
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe
Importance: High

Tracking:

Recipient	Read
'jay.kogoma@intertec.com'	
'dan.lehtonen@intertek.com'	
Janda, Michel D	Read: 7/29/2009 12:07 PM
Cornelius, Mary Jo	

Dear Mr. Kogoma,
I inadvertently sent you an abbreviated list of deficiencies. To correct this, I am sending a more detailed version that I believe will be more helpful to you.

After reviewing your third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, it appears that addition information is required. The following information is necessary to continue the review of this 510 (k).

1. Your review memo identifies predicate devices within the KZE (Nonelectrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.

2. Your review memo references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.

3. Your review memo references the maximum pressure delivered by the subject device as 650 psi. However, your memo does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids, however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion

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reached. Please ask the sponsor to provide the following information:

A. how the determination of less trauma was ascertained;
B. the amount of pressure generated by the device compared to the amount of pressure generated by hand on the syringe;
C. the expected penetration distance in different tissues under maximum pressure; and
D. the method used to ensure that the pressure generated does not exceed 650 psi.

As per this email, K092090 has been placed on hold until further correspondence is received. Please note that these deficiencies should not be considered as comprehensive as additional questions may arise during the review of the sponsor's response and your review memo.

Please feel free to contact me if you need clarification regarding these deficiencies. Hard copies of your response are required and can be directed to the FDA document center. Thank you.

Mary J. Cornelius, RN, BSN, CGRN
9200 Corporate Blvd.
Rockville, MD 20850
Email: mary.cornelius@fda.hhs.gov.
Phone: 240-276-4135
Fax: 240-276-4156

NEW after August 1, 2009

Mary J. Cornelius, RN, BSN, CGRN
WO66 RM 0204GH HFZ
10903 New Hampshire
Silver Spring, MD 20993
Email: mary.cornelius@fda.hhs.gov.
Phone: 301-796-6550

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 133

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

(·lius, Mary Jo

From: Cornelius, Mary Jo
Sent: Wednesday, July 29, 2009 11:02 AM
To: 'jay.kogma@intertek.com'; 'dan.lehtonen@intertek.com'
Cc: Janda, Michel D
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe
Importance: High

Dear Mr. Kogma,

After reviewing your third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, it appears that addition information is required. The following information is necessary to continue the review of this 510(k).

1. Please provide a copy of the protocol(s) for the Ex- Vivo and In-vivo Studies. The results of these studies are not sufficiently detailed to make an evaluation.

2. In section III, p4 you indicate that amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. Please provide the following information:

   A. how the determination of less trauma was ascertained;

   B. amount of pressure generated by the ERBELIFT Hand Pump compared to the amount of pressure generated by hand on the syringe;

   C. provide upper limit of pressure which results in perforation; and

   D. method used to ensure that pressure generated does not exceed 650 psi maximum listed.

As per this email, K092090 has been placed on hold until further correspondence is received. Please note that these deficiencies should not be considered as comprehensive as additional questions may arise during the review of the sponsor's response and your review memo.

Please feel free to contact me if you need clarification regarding these deficiencies. Hard copies of your response are required and can be directed to the FDA document center.

Thank you.
mjc

Mary J. Cornelius, RN, BSN, CGRN
9200 Corporate Blvd.
Rockville, MD 20850
Email: mary.cornelius@fda.hhs.gov.
Phone: 240-276-4135
x: 240-276-4156
W after August 1, 2009
ary J. Cornelius, RN, BSN, CGRN
WO66 RM 0204 G/H
10903 New Hampshire
Silver Spring, MD 20993
Email: mary.cornelius@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third party review, i.e.:		
a. Is the device on the list of eligible devices?*	Yes	No
b. Can a determination of substantial equivalence be made without clinical data?	Yes	No
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?	Yes	No

Unknown (UK)

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:		
a. The purpose of the submission	Yes	No
b. The name and address of the third party	Yes	No
c. The name and address of the 510(k) holder	Yes	No
d. The name of the device (trade name, common or usual name, and FDA classification name)	Yes	No
e. The third party's recommendation with respect to the substantial equivalence of the device	Yes	No
f. The date the third party first received the 510(k) from the 510(k) holder	Yes	No

3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	Yes	No

(UK)

4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	Yes	No

(UK)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	Yes	No

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6. A certification that:		
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	Yes	No
b. Statements made in the third party's review are true and accurate to the best knowledge of the third party	Yes	No
c. The third party's review is based on the 510(k) that it is submitting with the review	Yes	No
d. The third party understands that the submission to the government of false information is prohibited	Yes	No

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	Yes	No
b. Record of Deficiencies, if applicable (attachment 1a)	Yes	No
c. Indications for Use Form	Yes	No
d. 510(k) Summary or Statement (attachment 1c)	Yes	No
e. 510(k) Truthful and Accurate Statement (attachment 1d)	Yes	No
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)	Yes	No

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: See AI Request for Deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Janda, Michel D

From: Janda, Michel D
Sent: Wednesday, July 22, 2009 12:22 PM
To: Zimliki, Charles L* (CDRH)
Subject: Third party for endoscopic needle with fluid injection technology

Hi Chip,

ULDB has been reviewing a third party 510(k) for an endoscopic needle that uses manual powered fluid injection technology. I wanted to touch base with GHDB to see if this combination raises any concerns. I briefly spoke with Tony Watson about the device and he indicated that you were acting for General Hospital. We would like to get the file on-hold, but one of the deficiencies that we would like to add would change the regulation to the fluid injection reg. We think that the device should be reviewed in your branch because the injection technology is really the critical component. The endoscopic portion is really just an elongated tube. Please let me know if you agree with this approach and we will place the file on hold. When it comes back we will transfer it to your branch. Thanks.

Michel Janda
Acting Chief - Urology and Lithotripsy Devices Branch
ODE/DRARD
Phone #: (240) 276-4133
Fax #: (240) 276-4156

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I spoke with Mr. Colburn (Acting Chief, GHDB) on 7/28/09. He agreed that GHDB should review the device as a consult. It is unclear at this point in time if the device should be classified as 876.1500 or 880.5430. He is also unsure if the predicates are justified given the new Indications for use for needleless injection. A consult will be sent to GHDB when the submission comes off of Hold.

Michel Janda
Acting Chief, ULDB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Janda, Michel D

From: Janda, Michel D
Sent: Tuesday, July 14, 2009 3:42 PM
To: Watson, Anthony
Subject: Third party for endoscopic needle with fluid injection technology

Hi Tony,

ULDB just got a third party 510(k) for an endoscopic needle that uses manual powered fluid injection technology. I wanted to touch base with GHDB to see if this combination raises any concerns. I also wanted to inquire about the possibility of a consult for the fluid injection technology. Thanks.

Michel Janda
Acting Chief - Urology and Lithotripsy Devices Branch
ODE/DRARD
Phone #: (240) 276-4133
Fax #: (240) 276-4156

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 140

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DEPARTMENT of Health and Human Services

Food and Drug Administration
Center for Devices and Radiological Health

Memorandum

Date: July 20, 2009 mjc
From: M. J. Cornelius
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe

Contact: Daniel W. Lehtonen **Phone:** 937-313-7454 OH **FAX:** 330-405-5518
Email: dan.lehtonen@intertek.com
To: Record

Intended use The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in to the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Device Description: the Hand Pump is a gun-shaped component with a handle and a barrel (slot for mounting a syringe) used for the delivery of pressurized sterile normal saline. It is reusable and delivers approximately 0.75 ml of normal saline per squeeze of the handle. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of **145 to 650 psi, which** correlates to flow rates of **17 to 38 ml/minute**. The pressure and flow rate depend upon the number of times the handle is squeezed.

The Flexible Probe consists of a handle with a standard Luer lock connection hub and 260 cm catheter (tubing). Its distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 µm. It is provided as sterile and labeled for single use. The probe is 260 cm in length with an outer diameter of 1.3 mm and an inner diameter of 0.120 mm.

The ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe (previously cleared under K920135 is intended to be used as an accessory with the proposed device; however it is not provided with the device.

K920135 Angiographic injector and syringe. DXT 870.1650 MedRoyal Angiographic Control Syringe and Palm Plate/Thumb Ring

The four proposed syringes are as listed below.
10cc Syringe with a Fixed Male Luer Lock and a Thumb Grip
10cc Syringe with a Fixed Male Luer Lock and a Palm Pad
10cc Syringe with a Rotating Male Luer Lock and a Thumb Grip
10cc Syringe with a Rotating Male Luer Lock and a Palm Pad

Substantial equivalence is claimed to:
K924102 FBK endoscopic injection needle, gastroenterology-urology 876.1500

INTENDED USE: The U.S. Endoscopy needle is indicated for use with flexible gastroscopes, colonoscopes, sigmoidoscopes, duodenoscopes choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of fluids or tissue and for injection of medications or dyes into the tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-6118

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K040961 FBK endoscopic injection needle, gastroenterology-urology 876.1500 and **FDI** Endoscopic electrosurgical unit and accessories 876.1500
The Endoscopic Injection Needle/Snare is a dual channel device combines two devices into one combination device, which performs two separate functions electrosurgical snare and injection needle.

INTENDED USE: The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through a flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view. applying dye spray, clot removal, injection of hemostatic agents to control postpolypectomy bleeding, and tattooing of sites for future surgical purposes.

Animal study:
Ten (10) elevations were performed with the proposed needle-free elevation system and 1o with predicate needle injection system in a live porcine model (a >25 kg Yorkshire pig). The following data points were measured:

- Flow rate (ml/s)
- The volume (10 ml) of saline for the in-vivo **studies does not reflect the actual amount to be administered for the device use. This volume is selected solely to demonstrate the comparison between the proposed device and the predicate.**

Parameters Tested	Proposed ERBELIFT (Needle Less injection	K924102 Carr Locke (Injection Needle	Results
Ex- Vivo Study			
Mucosal lift (independent of endoscopist skill[1]	Accomplished in 100% 10 cases	Accomplished in 92%	Mucosal lift was greater with the ERBELIFT
Perforations	None	None	
Ease of use[2]	in 92% cases	in 64% cases	
Accuracy	< 3mm in 100% cases	3mm in 76% cases	proposed device reported comparatively accurate[3]
Height of elevation	15.27 ±4.99 mm	15.84 ±5.5 mm	no statistical difference
Flow rate	061 ± 009 mils	053 ± 023 mils	no statistical difference
Total procedure time	19.36 ±3.35 sec.	28.2' ± 8.85 sec.	ERBELIFT resulted in reduced procedure time
Maximum lift diameter	40.18±10.26 mm	33.03 ± 11.31 mm	Mucosal lift was greater with the ERBELIFT

1. Endoscopist skill level: 5 endoscopists (2 master clinicians, 2 trainees, 1 novice)
2. Ease of use is defined as simple, fair, unacceptable. This is a subjective determination and therefore of little use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 1 92

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

In vivo studies performed by 3 endoscopists, (1 master clinician, 1 trainee, 1 novice)

In- Vivo Study			
Flow rate	0.39 ± o.o5 mils	0.36 ± o.o7 mils	no statistical difference
Perforations (at maximum force)[3]	None	None	

3. Perforation risk at maximum force. Defined as the maximum pull/activation force applied to the trigger of the hand pump by the user who is deliberately ignoring the visual tissue effect - essentially simulating negligent use of the product.

Conclusion: The predicates (K040961 and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. The proposed device with a needle-free system and Hand Pump is also designed to lift polyps or other mucosal lesions. The differences technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 μm in diameter (compared to 810 μm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

1. Please Identify a predicate device that more accurately compares to the ERBELIFT Hand Pump and Flexible Probe
   FDA believes that the product code selected FBK (endoscopic injection needle, gastroenterology-urology) does not accurately describe the device design. The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is designed to deliver a needleless injection of pressurized saline. Both the "needless" feature and "mechanical pressurized" are more accurately described as KZE under CFR 880.5430
   "A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations".

2. Please demonstrate compliance with ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods.

3. Please provide a copy of the protocol(s) for the Ex- Vivo and In-vivo Studies. The results of these studies are not sufficiently detailed to make an evaluation.

4. In section III, p4 you indicate that amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. Please provide the following information:

   A. how the determination of less trauma was ascertained;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 143

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

B. amount of pressure generated by the ERBELIFT Hand Pump compared to the amount of pressure generated by hand on the syringe;

C. provide upper limit of pressure which results in perforation; and

D. method used to ensure that pressure generated does not exceed 650 psi maximum listed.

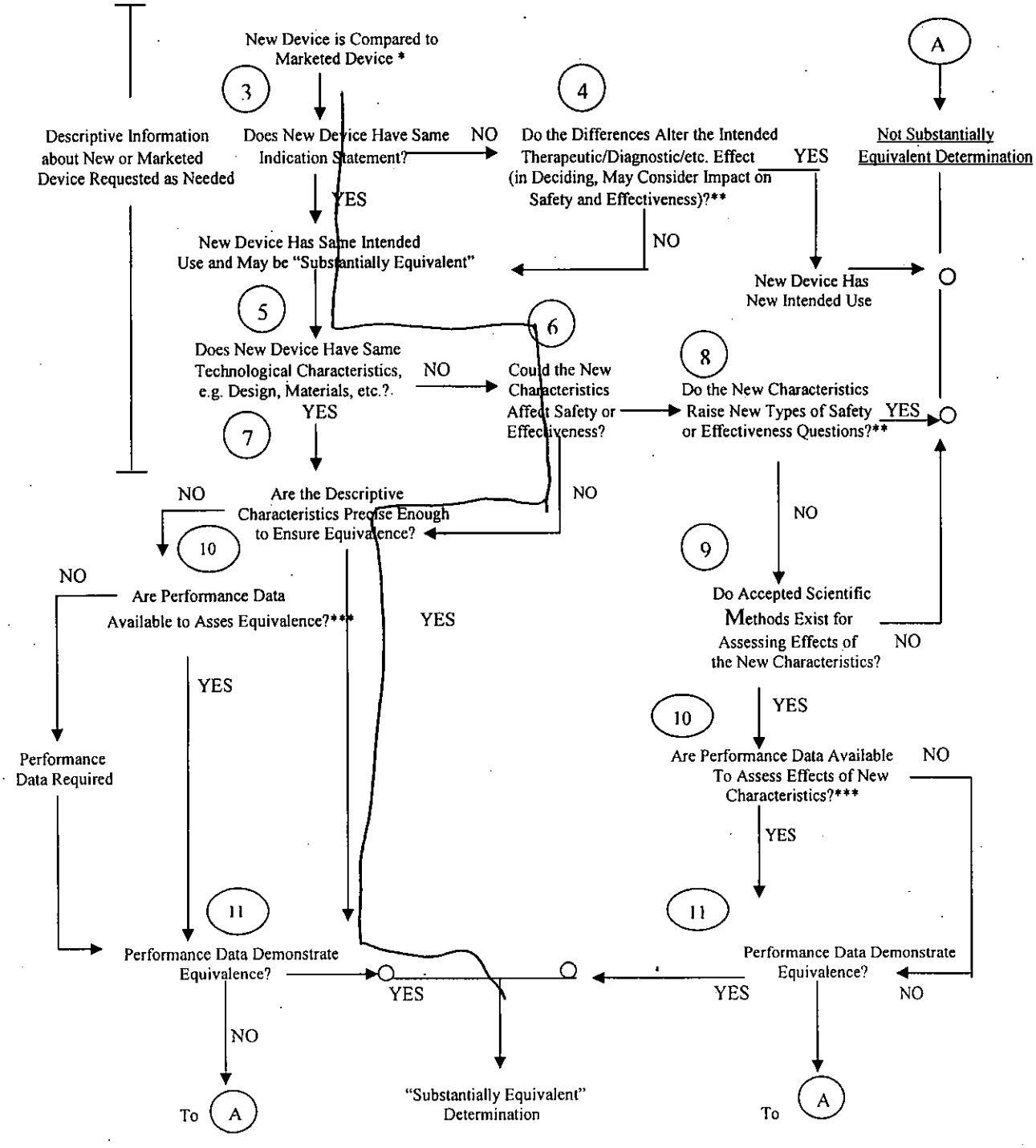
I have informed the sponsor on hold pending receipt of additional information

Branch Chief Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 4/4/

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 29, 2009

BYRNE MEDICAL INC.
c/o INTERTEK TESTING SERVICES
2307 EAST AURORA ROAD UNIT B7
TWINSBURG, OHIO 44087
UNITED STATES
ATTN: DANIEL W. LEHTONEN

510k Number: K092090

Product: ERBELIFT HAND PUMP AND FLEXIBL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

K092090/S1

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012

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28 Sep 2009

Supplemental Information for K092090

FDA CDRH DMC

SEP 29 2009

Received

CDRH Document Mail Center
Mailstop HFZ-401
Attention: THIRD PARTY REVIEW / Ms. Cornelius
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Ms. Cornelius,

Enclosed with this letter are the updated Third Party Review documents for the Byrne Medical, Inc. ERBELIFT™ Hand Pump and Flexible Probe device being reviewed under K092090. The information being provided includes the following:

1. This cover letter
2. Revised Review Memo with information addressing FDA questions (starts on page 1)
3. Supplemental information from the Firm (Appendix A1.3 of the review memo)

Should you have additional questions or require additional information please let me know.

Respectfully Yours,

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices

K43

BEAB Approved

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Processed under FOIA Request #2011-1895; Released by CDRH on 03-07-2012

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Premarket Notification [510(k)] Review
Traditional/Abbreviated
K092090

Date:	09 Jul 2009 **[Revised 25 Sep 2009]**		
To:	The Record	Office:	
From:	Daniel W. Lehtonen Intertek Testing Services NA, Inc. 3rd Party Review Memo	Division:	

510(k) Holder:	Byrne Medical, Inc.
Device Name:	ERBELIFT™ Hand Pump and Flexible Probe
Contact:	Mr. Chris Hierholzer
Phone:	(936) 539-0391
Fax:	(936) 539-2381
E-mail:	chierholzer@byrnemedical.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce (ERBELIFT™ Hand Pump and Flexible Probe) into interstate commerce.

Comments added 25 Sep 2009

This review memo was modified in response to FDA comments with the inclusion of the following tabulated responses:

Item	Description of Deficiency
1. **FDA Finding:**	Your review memo identifies predicate devices within the KZE (Non-electrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5640 SD014 (18 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	Along with the two (2) recognized consensus standards stated, many other standards were considered. Each standard was carefully evaluated for the appropriateness/relevance with the ERBELIFT™ Hand Pump and Flexible Probe. Both of the stated standards were determined not to be applicable as follows: A. ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods In the "Introduction" of the standard and a consistent theme throughout the standard is its application "to needle free injectors to administer medicinal products". The primary concern and testing referenced in the standard involves dosages (i.e. intended, ejected, maximum/minimum, etc.). These issues are not applicable to our product as with the predicate (i.e., sterile normal saline used when being introduced into the submucosa for lifting polyps and other lesions under direct visualization through an endoscope.). The ERBELIFT™ Hand Pump and Flexible Probe are used to provide an effect (i.e. lifting/cushioning) and not to deliver medicine. The Hand Pump is not a "Jet" injector as classified in product code KZE. There is no static force mechanism within the device (e.g. there is no spring loaded, CO_2 or pneumatically driven, etc. force.). A squeeze of the Pump's handle makes it easier for a clinician to move a syringe plunger a fixed distance as compared to manually pushing a plunger of the syringe. In both the predicates' and the proposed device, force is applied to the plunger in order to move fluid via a lumen into the submucosa. B. ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes The scope of this standard involves reusable, heat-stable endoscopic accessory instruments (EAI) designed to be inserted into flexible endoscopes. The ERBELIFT™ Hand Pump is reusable, but it is not intended to be inserted into a scope, nor could it be. (Note: As with mechanical endoscopic lavage pumps which are 510(k) exempt, it is to be cleaned/disinfected with a hospital grade disinfectant. The Pump does not come in contact with the patient or the fluid pathway.) The ERBELIFT™ Flexible Probe is inserted into the endoscope. It is single use and disposable. The other involved accessories (syringe and sterile normal saline) are single use and disposable.
Closed Out:	25 Sep 2009 The firm addressed the reasoning for not using the identified standards as the standards do not apply to the device. The response addressed the issue.

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
2.	**FDA Finding:**	Your review memo references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.
	Response:	The concept, product design, testing, etc. of the ERBELIFT™ Hand Pump and Probe followed design control requirements. Included are the following Exhibits of the work performed to support the efficacy and safety of the proposed device: Exhibit 1, Rationale to Support Substantial Equivalence Summary: A rationale to determine the specific aims, goals, methodology, and acceptance criteria for the ERBELIFT™ Performance Testing (specifically, Ex-Vivo and In-Vivo testing) was developed in order to support substantial equivalence. Exhibit 2, ERBELIFT™ Performance Test Plan (Note: Results/Conclusions are Included) Summary: The test plan was devised in collaboration with Dr. David Carr-Locke, Director, The Endoscopy Institute, Brigham and Women's Hospital, Harvard Medical School, Boston, MA. Based upon the rationale, the test plan provides the strategy and the relationship between the specific goals and aims of the individual test protocols and reports used to support substantial equivalence to the predicate. Regarding the evaluation process of ERBELIFT™ per Dr. Carr-Locke: *"For the development of EMR devices, it is well-established in the research and clinical fields within gastroenterology that the response of porcine gastrointestinal mucosa, submucosal and muscularis propria to fluid injection, manipulation and resection accurately reflect the behavior of human tissue to these same procedures."* Two of the specific goals/aims were: 1. Effectiveness of creating a submucosal elevation/lift under direct endoscopic visualization, 2. Performance outputs comparable to an injection needle in the Ex-Vivo testing using porcine stomach and In-Vivo testing in porcine colon.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5118.
SD14.1 (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	Exhibit 3, Testing Report (Results) of Feasibility Protocol, Ex-Vivo Trial 1 Summary: An evaluation of the technical feasibility of a needle-less method to create a submucosal elevation/lift using the ERBELIFT™ Hand Pump and Flexible Probe. Exhibit 4, Study Protocol and Report, Ex-Vivo Trial 2 Summary: An evaluation to have the most optimal technique (method) to create a submucosal elevation/lift using the ERBELIFT™ Hand Pump and Flexible Probe compared to the standard injection needle method. Exhibit 5, Testing Protocol and Report, In-Vivo Trial Summary: An evaluation of the performance outputs of the ERBELIFT™ Hand Pump and Flexible Probe compared to the standard injection needle. Support to address each part of Question 2 is as follows: A. In reference to complete reports for this testing, a summary of the testing was provided in the initial submission. See summary of Results of each Trial in Exhibit 2 and Protocols as applicable and Reports in Exhibits 3, 4, and 5. B. Regarding the performance of the subject device, please see summary of Results of each Trial in Exhibit 2. C. In response to test protocols and test results for the animals, see Exhibits 3, 4, and 5. D. Specific to your comments about our review memo, as the result of the three (3) phases of testing, it was concluded that: 1) The ERBELIFT™ Hand Pump and Flexible Probe were effective in creating a submucosal elevation/lift under direct endoscopic visualization. 2) The performance of the ERBELIFT™ Hand Pump and Flexible Probe was comparable to an injection needle. 3) No additional safety concerns were raised with using the ERBELIFT™ Hand Pump and Flexible Probe. If further explanation of this process and its applicability to clinically-approved methodology is required, Dr Carr-Locke is willing, as one of the authors of the Ex-Vivo and In-Vivo Performance Test Protocols, to provide additional information, expertise, and discussion. E. Regarding additional expertise required, please see comment above in D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-ISO-ATS@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency	
Closed Out:	25 Sep 2009	
	FDA Issue 1:	Please ask the sponsor to provide the test protocols and results for these animal studies.
	3rd Party:	The firm provided copies of the following supporting documents:
	• Exhibit 1:	Rationale to Support Substantial Equivalence
	• Exhibit 2:	ERBELIFT™ Performance Test Plan (Results / Conclusions are Included)
	• Exhibit 3:	Testing Report (Results) of Feasibility Protocol, Ex-Vivo Trial 1
	• Exhibit 4:	Study Protocol and Report, Ex-Vivo Trial 2
	• Exhibit 5:	Testing Protocol and Report, In-Vivo Trial
	FDA Issue 2:	Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing.
	3rd Party:	The protocols provided by the firm outlines the feasibility for their device, details of the protocols used including the basis for the porcine model and test methods, goals for each of their studies (ex-vivo and in-vivo) and results to show that the device met the firm's acceptance criteria and performed equivalently to the predicate device. See appendix A1.3 to this review memo for the firm's response and supporting documentation.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHOCESTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
3. FDA Finding:	Your review memo references the maximum pressure delivered by the subject device as 650 psi. However, your memo does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids; however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information: A. how the determination of less trauma was ascertained B. the amount of pressure generated by the device compared to the amount of pressure generated by hand on the syringe C. the expected penetration distance in different tissues under maximum pressure and D. the method used to ensure that the pressure generated does not exceed 650 psi

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Questions? Contact FDA/CDRH/OCE/DID at CDRHPROSTATUS@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	The submission referenced a maximum pressure delivered by the subject device as 650 psi, however, this value was only a theoretical maximum pressure limit which was not attainable in practice independent of the force applied to the ERBELIFT™ Hand Pump by the individual test subjects (please see Exhibit 3). The Technical Feasibility Study was carefully designed and included flow rate and pressure monitoring for both the subject and predicate devices in order to ascertain and compare the operating pressures associated with the predicate device under normal use. In addition, we were also able to determine the minimum flow rate and pressure (used to measure force) required to breach the mucosa with the saline stream. Unlike when manual pressure or force is applied to the predicate device in order to breech the mucosa, once the minimum flow rate is achieved to breech the mucosa with the subject device, the water stream slows very rapidly (please reference Exhibit 1 for a detailed overview of the procedure). Our experimental study design did include "worst-case scenario testing" (quick hard trigger pulls in order to achieve the highest flow rates during in-vivo testing in pig colon- thinnest wall anatomy). In summary, the subject tissues were excised and a leak test was performed in order to detect perforations. No perforations were detected (For a detailed summary, please see Exhibit 5). The answer to the subset questions are: A. The ERBELIFT™ Hand Pump and Flexible Probe is less traumatic to tissue because: i. A small fluid stream from the tip of the probe pierces the mucosa as compared to a larger stainless steel needle of the predicate. ii. The fluid stream delivered by the subject device is 0.120 mm as compared to a needle tip's outer diameter which is approximately four (4) times larger (0.508 mm). Trauma can be associated with the size of the tissue defect. iii. The fluid delivered is incrementally controlled (i.e. a maximum 0.75 ml is delivered per pull) with the Hand Pump.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-OISPATCHES@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	B. While similar pressures and flow rates can be achieved with the subject and predicate devices, the variability in pressure that can be generated by pushing on the syringe plunger depends upon the individual operator. When the trigger of the Hand Pump is squeezed faster, the flow rates and pressures increase just like when the plunger is manually pushed harder with predicate devices. The key here is that with both the proposed and predicate devices, lifting is performed under direct visualization. Regarding comparison of flow rates and pressures, see Exhibit 3. C. Unlike the predicate needle device which uses a solid needle to "blindly" find the submucosal tissue plane (by trial and error, please see Exhibit 1), a **minimum** pressure or fluid flow rate is utilized to penetrate the mucosa with the subject device. As soon the fluid stream comes in contact with resistance (i.e.-tissue, fluid collection in the submucosa), the fluid continues to follow the path of least resistance and collect in the submucosa. Our "worst case scenario testing" failed to perforate even the thinnest wall anatomy in an in-vivo environment meaning only a mucosal breech was possible. D. There are several factors which influence maximum pressure. The size of the orifice, diameter of the syringe, length of the device or flow channel, etc... For example, a smaller orifice and or smaller diameter syringe or both would lead to extremely high pressures; however, the flow rate may be so low that it does not provide the desired tissue effect. Except for the differences between individual operators (cannot be controlled with the predicate device), the mechanical drive, orifice size, syringe, and probe limit the maximum flow rate. Both the predicate and subject devices operate with very similar flow rate variability.
Closed Out:	25 Sep 2009 The firm provided a very detailed response to the questions raised and explained how the device operates with respect the pressures - with 650 psi being the maximum generated during intentional mis-use of the device. During normal use, the data provided by the firm shows that the device operates at the same pressures as the predicate. The "less trauma" comment is based upon the fluid stream delivered by the subject device is 0.120 mm as compared to a needle tip's outer diameter which is approximately four (4) times larger (0.508 mm). The smaller diameter penetration would result in less trauma tissue trauma based on the lower diameter. The expected tissue penetration would be limited to the penetration of the mucosa since the fluid would spread out into the sub-mucosa layer in the same way that the predicate device does. The primary difference between the devices is the method used to penetrate the mucosa - the predicate uses a needle and the subject device uses a fluid stream. Once the fluid reaches the sub-mucosa a bleb forms in both cases.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Original Comments

The proposed ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. The proposed system encompasses following design changes as compared to the predicates cleared under K040961 and K924102

- The Hand Pump is included as an additional component for the proposed device to provide mechanical force to the syringe used for saline delivery as compared to the predicates with needle injection system which only utilized a syringe.

- The working diameter (1.3 mm) of the ERBELIFT Flexible Probe is smaller as compared to the sheath working diameter (2.5 / 3.0 mm) for the Carr Lock Injection Needle System / I-Snare System predicates. Also, the ERBELIFT Flexible Probe tip has a smaller inner diameter of 0.120 mm as compared to the predicate 25 G needle tip with an outer diameter of 0.508 mm and an inner diameter of 0.241 mm used with the predicates.

- The materials used for the Flexible Probe and Hand Pump are different compared to the predicates. The Flexible Probe is made of Nylon and stainless steel, whereas the Hand Pump is made of Polyetheretherketone (PEEK) and Nylon. Medical grade inks / reducer are used to imprint logos on the Probe. Additionally, a Genesolv S-T solvent is used to clean the Probe tip prior to treatment.

Overall, the technological characteristics of the proposed device are different as compared to the predicates that utilize a needle for injection. However, these technological characteristics are comparable to that of the needle-free injection devices or jet injectors for the same intended use. Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

The proposed system employs a needle-free mechanism and does not puncture the tissue. Instead, the combination of the force of the saline applied via the Hand Pump / syringe combination and the placement of the flexible probe enables for the saline to be inducted through the tissue and disperse into the submucosal layer. This process allows the user to achieve their desired polyp lift. The pressure and flow rate of saline delivery depend upon the speed with which the Hand Pump handle is squeezed (the more times the users squeezes the handle over a given time the higher the pressure and flow rate). However, each squeeze of the handle delivers 0.75 ml (approx.) saline, thus the user has control of how much saline is being delivered.

The materials used for the proposed system have a history of safe medical use and the firm provided adequate biocompatibility testing to substantiate these material changes (as summarized in Section VIII of this Review Memo). Also, the firm provided ex-vivo and in-vivo performance testing (animal based) to demonstrate the efficacy of the proposed device in comparison to the predicate K924102. The performance data showed the device provides equivalent performance to the predicate with no increased safety concerns. Based on the information provided, the design / material changes do not raise any new questions in terms of safety or effectiveness of the proposed device.

Therefore, based on the information provided by the firm's submission, the ERBELIFT Hand Pump and Flexible Probe is substantially equivalent to predicate devices cleared under K040961 and K924102, with respect to indications for use, performance, and labeling and that the technological changes do not introduce new safety or effectiveness questions as shown in the firm's submission and summarized in this review memo.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5118
SD104 rev 16 (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: **Prescription Use**)	Before submission TOC	X		
Truthful and Accuracy Statement	Section II, Page 1	X		
510(k) Summary or 510(k) Statement	Item 2, Sub-Tab 07Jul2009, Tab 7	X		
Standards Form	Section III, Pages 13-15	X		

Note: Reference to "Tab 7" in the above table refers to the 3rd Party Review Binder. Section numbers refer to the firm's original submission.

The above administrative documents were provided by the sponsor and found to meet the FDA requirements at the present time.

A copy of the final Indications for Use Form and a copy of the final 510(k) Summary are located behind the 3rd Party Submission Cover Letter in Tab 1 and copies of FDA form 3654 for all standards referenced in the submission are located in Tab 2 of the Third Party Review Binder.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X*	X*	
Is the device reusable (not reprocessed single use)?	X*	X*	
Are "cleaning" instructions included for the end user?	X		

* The proposed ERBELIFT system consists of a Hand Pump and a Flexible Probe. The Hand Pump is reusable and provided non-sterile, whereas the Flexible Probe is labeled for single use and provided sterile. Adequate cleaning and reprocessing instructions for the Hand Pump are provided in the Instructions for Use Manual (see Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder).

The ERBELIFT Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe (previously cleared under K920135) is intended to be used as an accessory with the proposed device; however it is not provided with the device. The syringe is filled with sterile normal saline and is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Probe is primed with the saline and then its distal end is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target (submucosal) tissue without puncturing the mucosa. The handle of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the submucosal bed of the polyp or lesion to achieve a desired tissue lift.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5700 SD101 (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Device Component	Specification	
	Dimensions	**Materials**
Hand Pump	Length: 8-3/4" (22 cm) Thickness: 2-1/2" (6 cm) Width: 6" (15 cm)	Nylon and stainless steel
Flexible Probe	Length: 260 cm Outer Diameter: 1.3 mm Inner Diameter (jet stream): 0.120 mm (120 µm)	Polyetheretherketone (PEEK) and Nylon (Medical grade inks and reducer are used to imprint logos on the Probe)

The Hand Pump is a gun-shaped component with a handle and a barrel (Slot for Mounting a Syringe). It is reusable and delivers approximately 0.75 ml of normal saline per squeeze of the handle. The Flexible Probe consists of a handle with a standard Luer lock connection hub and catheter (tubing). Its distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 µm. It is provided as sterile and labeled for single use. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute. The pressure and flow rate depend upon the number of times the handle is squeezed.

Note: The firm provided product pictures and engineering drawings for the proposed ERBELIFT Hand Pump and Flexible Probe, which can be located in Section IV of the original submission.

IV. Indications for Use

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Discussion: The Indications for Use of the proposed ERBELIFT Hand Pump and Flexible Probe are comparable to that of the predicates. Like the predicates, the function of the proposed device is the same in that the devices are intended for the delivery of fluids into the submucosal tissue for endoscopic purposes. The lifting medium (sterile normal saline) is a part of the types of solutions identified for use with the predicates. There are no new indications.

Therefore, the proposed device is substantially equivalent to the predicates in this regard.

V. Predicate Device Comparison

The firm identified the following predicate devices:
K924102 [Cleared 25 Nov 1992], K040961 [Cleared 08 Jul 2004]

The firm has provided a comparison table in **Section III (Pages: 5-10)** of the original submission (as shown in the below table). Review of the comparison tables show that the new device has the same characteristics as the predicate devices and supports the sponsor's claims.

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Manufacturer and 510(k) Applicant	United States Endoscopy Group, Inc.	United States Endoscopy Group, Inc.	Byrne Medical, Inc.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
510(k) Number	K924102	K040961	TBD
Indications For Use	Intended Use in 510(k)*: The U.S. Endoscopy needle is indicated for use with flexible gastoscopes, colonoscopes, sigmoidoscopes, duodenoscopes, choledochoscopes, nephrofiberscopes and bronchoscopes for aspiration of fluids or tissue and for injection of medications or dyes into tissue.	Intended Use in 510(k)*: The dual lumen Injector Needle Snare is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.	The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.
Materials			
Hand Pump	Not Applicable	Not Applicable	Plastic and Stainless Steel
Needle or Probe	Plastics, Teflon, Metal, Stainless Steel	Plastics, Metal, Stainless Steel	Plastics and Medical Grade Inks with Reducer
Physical Characteristics			
Hand Pump	Not Applicable	Not Applicable	A Gun Shaped Device with a Handle and a Slot for Mounting a Syringe

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Needle or Probe	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle	Handle with a Standard Luer Lock Connection Hub, Catheter (Tubing) with Extension Needle and Snare	Handle with a Standard Luer Lock Connection Hub and Catheter (Tubing)
Dimensions			
Hand Pump	Not Applicable	Not Applicable	Barrel Length: 8-3/4" (22 cm) Width (Top of Barrel and Handle): 6" (15 cm) Thickness (Width of Barrel): 2-1/2" (6 cm)
Needle or Probe	Working Length: 230 cm Working Outer Diameter (O.D.): 2.5 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm	Working Length: 230 cm Working Outer Diameter (O.D.): 3.0 mm Needle Maximum Extension: 5 mm Needle Gauge: 25 G (O.D. 0.508 mm)/Inner Diameter-Stream: 0.241 mm/ 241 µm Snare Maximum Extension Width: 2.5 cm	Working Length: 260 cm Working Outer Diameter: 1.3 mm Tip Inner Diameter/ Stream: 0.120 mm/ 120 µm
Force / Flow Rate	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	Unknown- Dependent Upon Force Applied by Needle and on Plunger of Syringe	145 to 650 psi / 17 to 38 ml/minute

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Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Labeling			
Hand Pump	Not Applicable	Not Applicable	Carton Label and Instructions For Use
Needle or Probe	Outer Packaging Labels and Instructions For Use	Outer Packaging Labels and Instructions For Use	Outer Packaging Pouch, Carton, and Case Labels as well as Instructions For Use
Condition Provided/ Use Condition			
Hand Pump	Not Applicable	Not Applicable	Non-sterile/ Reusable
Needle or Probe	Sterile/Disposable-Single Use	Same	Same
Sterilization Method Used by Manufacturer			
Hand Pump	Not Applicable	Not Applicable	Not Sterilized
Needle or Probe	Ethylene Oxide	Same	Same
Cleaning/Disinfection			
Hand Pump	Not Applicable	Not Applicable	Method in Notes On Use
Needle or Probe	Not Applicable	Same	Same
Required Accessory	Syringe	Syringe	Syringe [Not included with the device - Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings); 510(k) Number K920135]

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Characteristics	Predicate Devices		Proposed Device (ERBELIFT™ Hand Pump and Flexible Probe)
	Injection Needle	Injection Needle/Snare	
Delivered Medium/ Solutions	Medicinal Sub-stances and Solutions as Follows: Sodium Morrhuate, Sodium Tetrade-cylsulfate, Ethy-nolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotrad-ecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Medicinal Sub-stances and Solutions as Follows: Sodium Morrhuate, Sodium Tetrade-cylsulfate, Ethy-nolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotrad-ecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media	Sterile Normal Saline Note: Also, referred to as 0.9%NaCl or Physiological Saline. It is a specific concentration of "Hypertonic Saline".
Target Population	Endoscopic Patient Candidates with Polyps or Mucosal Lesions	Same	Same
Anatomical Site	Esophagus, Stomach, Duodenum, Small Intestine, and Large Intestine	Same	Same
FDA Guidance Documents Used	Unknown	Unknown	Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s, 8/12/05

The following major differences were identified from the device to the predicate(s). A justification of how these differences is determined that the device is substantially equivalent to the predicate is also provided. All other differences are considered minor and a justification is not required.

1. The Hand Pump is included as an additional component for the proposed device to provide mechanical force for saline delivery (fluid induction method) as compared to the predicates with needle injection system.

2. The working diameter (1.3 mm) of the ERBELIFT Flexible Probe is smaller as compared to the sheath working diameter (2.5 or 3.0 mm) of the predicates.

3. The ERBELIFT Flexible Probe tip has a smaller inner diameter of 0.120 mm as compared to the predicate 25 Ga. needle tip with an outer diameter of 0.508 mm and an inner diameter of 0.241 mm. The working length of the Probe is 260 mm.

   Discussion: The predicates (K040961 and K924102) utilize the force of the fluid (hand pushed from the syringe) through the needle to lift polyps or other mucosal lesions. For the propsoed device with a needle-free system, the Hand Pump is included to provide the force to the control

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syringe for inducing the pressurized fluid into the submucosa to achieve desired lift. This technological characteristic of the proposed device is comparable to that of the needle-free injection devices or jet injectors Using mechanical compression to force fluid through a small orifice, these needle-free injection devices can produce high-pressure stream 76 to 360 µm in diameter (compared to 810 µm for a 21-gauge needle) that could penetrate the skin and subcutaneous tissue.

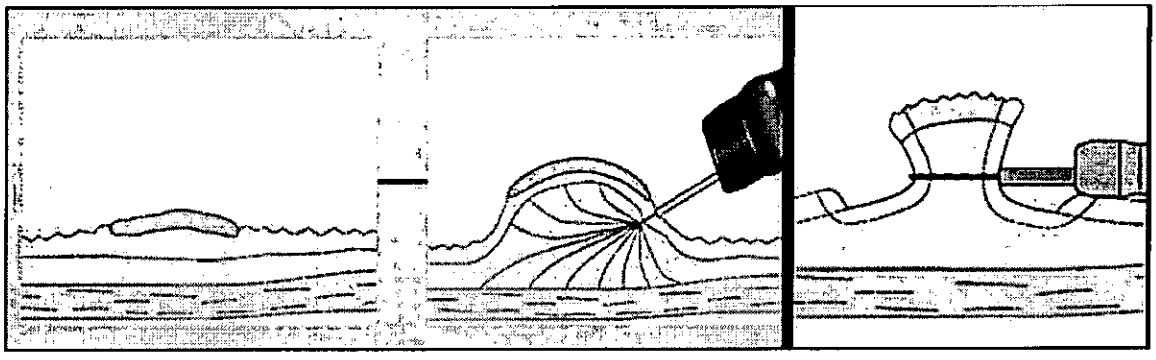

Fig 1: Schematic of submucosal elevation achieved using ERBELIFT Flexible Probe & Hand Pump

While the predicates employ needle system to puncture and penetrates the tissue, the proposed device Probe is not intended to puncture the mucosa. Instead, the Probe is placed against the mucosa and the hand pump handle is squeezed. With each squeeze of the handle, a fixed volume of saline is released from the control syringe. The release of saline in the GI tract results in the expansion of the surrounding tissues. However, within the GI tract, the mucosa, muscularis proproa and the serosa do not retain the saline and hence do not allow for the formation of saline bleb (localized collection of the fluid). Also, since the fluid property is to seek the path of least resistance, the saline travels to the aerolar tissue of the submucosal layer. The submucosa is a dense irregular layer of connective tissue with large blood vessels, lymphatics and nerves and is located beneath the mucosa. It allows for the dispersion of saline and hence leads to formation of a bleb of saline in the polyp bed. This bleb formation results in a marked elevation of the polyp and thereby creates the lift (See Fig. 1).

The smaller outer diameter and fluid stream of the ERBELIFT Flexible Probe causes less penetration damage to the tissue as compared to predicates. With the amplified force from the Hand Pump, the saline disperses in the submucosa without actually puncturing the mucosal tissue. Therefore the chances of complications like bleeding and laceration are comparatively reduced as compared to the predicates. Also, the Performance (ex-vivo and in-vivo animal tests) results demonstrated that there were no perforations with the use of proposed device (see Section XI of this Review Memo). Further, the working length of the flexible probe (260 mm) is comparable to that of the predicate needles (230 mm). The design of the Hand pump and the fixed volume of the saline (0.75 ml per squeeze of the handle) limit to allow the user to control the saline delivery volume.

Therefore, the modifications of having a Hand Pump as well as a Flexible Probe (with a smaller working diameter and tip configuration) do not raise any new concerns or impact the safety or effectiveness of the device.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

4. The materials used for the Flexible Probe and Hand Pump are different compared to the predicates.

   Discussion: The proposed device flexible probe is made of Nylon and stainless steel, whereas the hand pump is made of Polyetheretherketone (PEEK) and Nylon. Additionally, Medical grade inks / reducer are used to imprint logos on the Probe and the Genesolv S-T solvent is used to clean the Probe tip.

   The firm provided adequate biocompatibility data (including the material specification sheets and test reports, as summarized in Section VIII of this Review Memo) to substantiate the change and there is not impact on safety or effectiveness of the device.

VI. Labeling

The firm provided labeling for the proposed device which can be located in **Section V (Pages: 29-31)** of the original submission. The final version of the Instructions for Use manual can be located in Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder.

Overall, the labeling contains the following:

- Intended Use Statement
- Directions for Use
- Relevant Contraindications, Warnings, and Precautions
- Prescription Use Statement
- Marketing statements / claims

The Hand pump is a reusable component of the proposed device. It can be reused for up to 100 procedures and is required to be cleaned by wiping with water and hospital grade disinfectant prior to each use.

Overall, the proposed device labeling provides adequate information for operating and reprocessing the device. Adequate justification has been provided for the marketing claims and statements. The user manual also outlines the steps for the device preparation and its usage with the endoscope.

Additionally, the firm provided predicate user manuals (see Section V of the original submission, Pages: 1-28 for details) for comparison with the proposed device labeling. Review of predicate labeling does not raise any new concerns that would impact the safety / effectiveness of the proposed device.

Therefore, the proposed device is substantially equivalent to the predicates in this regards.

VII. Sterilization/Shelf Life/Reuse

The firm provided sterilization information for the proposed device, which can be located in **Section III, Page 31** of the original submission.

The proposed ERBELIFT system consists of a Hand Pump and a Flexible Probe. The Hand Pump is reusable and provided non-sterile, whereas the Flexible Probe is labeled for single use and provided sterile. The Sterilization Validation was carried out per the standard method described in ANSI / AAMI / ISO 11135-1:2007. The method used is Ethylene Oxide sterilization and the Sterility Assurance Level (SAL) is stated as 10^{-6}.

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Product: ERBELIFT™ Hand Pump and Flexible Probe

The Probe is placed in a protective sheath and then packaged in a Tyvek Pouch, suitable for Ethylene Oxide sterilization and designed for maintaining its integrity. The firm has stated that the ethylene oxide residual levels will be evaluated per AAMI / ANSI / ISO 10993-7:1995 and that prior to the distribution of the ERBELIFT Flexible Probe, the residual levels for each product will not exceed the following:

Ethylene Oxide (EO)	Ethylene Chlorohydrin (ECH)
20 mg in the first 24 hours	12 mg in the first 24 hours

There are no new concerns from the sterilization standpoint. Therefore, the proposed device supports the substantially equivalent determination in this regard.

VIII. Biocompatibility

Biocompatibility information is included in **Section III, Page 18** of the original submission. The proposed ERBELIFT Flexible Probe is categorized as being in limited contact (<24 hours) with gastrointestinal tissue during Endoscopic Surgery (Note: Contact time ranges from a few seconds to five (5) minutes).

The firm provided compliance assessment for ISO 10993-1 in Section III, Page 16 of the original submission. Additionally, an expert report from Dr. Bill Bradbury was provided to address the biocompatibility of the direct / indirect patient contacting materials. The report provided information regarding the long history of their biocompatibility as well as their use in medical applications (e.g., disposable medical instruments, such as catheters and shunts). The report can be located in Item 4, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder.

The firm provided MEM elution report to demonstrate the cytotoxicity testing of the Flexible Probe. The results demonstrated that the materials are non cytotoxic.

Material (including adhesives)	Summary of Testing
Victrex Polyetheretherketone (PEEK)	MEM Elution Test (Cytotoxicity Testing) Cell Line: Mouse Hetroploid Connective Tissue (L-929) Incubation Period: 72 ± 3 hours at 37 ± 1 °C Amount tested / Sample extract: 200.5 cm^2 / 66.8 mL Result: Non cytotoxic See Item 4, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder for details
Nylon 11 (white)	
Colorcon MD-1185 No-Tox Black Ink and Colorcon MD-1210 Reducer	
Genesolv-ST Solvent	

Note: the firm stated that the biocompatibility testing was performed on the final finished sterile Flexible Probe and as per GLP guidelines.

Below is the summary of the component materials that are intended for direct and indirect patient contact.

Victrex PEEK (Polyetheretherketone)

The Catheter Shaft and the tip of the Flexible Probe are made of Victrex PEEK, which is the same material used for the Catheter Shaft of the ERBEJET2 Flexible Probe (previously cleared under K072404). The Probe tip may come in brief contact with the tissue compromised during injection of the saline, however; it is not intended to penetrate the tissue. The Shaft passes through a lumen in

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the endoscope and only a couple of centimeters of the shaft and the tip, exiting the distal end of the endoscope, will have direct contact with the gastrointestinal mucosal tissue.

Nylon 11 (White)
The Luer Hub is made of white Nylon 11 and is over-molded onto the proximal end of the 260 cm long catheter shaft. The Hub and strain relief are on the outside of the proximal end of the Probe and have no direct contact with gastrointestinal tissue of the patient. The inner lumen of the Hub has indirect contact through the normal saline that passes through the Probe and is force-induced into the tissue. A material specification sheet has been provided for Titanium dioxide, which is a pigment added to form Nylon 11 (White).

Colorcon Black Ink (MD-1185) & Colorcon Reducer (MD- 1210)
They are used to print the ERBE Logo on the distal tip of the Probe and hence have a direct contact with the gastrointestinal mucosal tissue.

Genesolv-ST solution
It is used to clean a portion of the distal tip of the Probe, prior to printing and hence will have a direct contact with the mucosal tissue.

The firm provided material specification sheets for the above mentioned direct / indirect patient contacting materials which can be located in Item 5, Sub-Tab 01 Jul 2009, Tab 7 of the Review Binder.

Note: The strain relief for the Probe is made of Nylon 11 (clear), which is a non-patient contacting material. The Genesolv-ST cleaner, Colorcon MD-1185 black ink, and Colorcon MD-1210 reducer have a history of safe use (e.g. with Medron Inc.'s processing of BARD Access System Catheters such as Groshong & PerQ-Cath Medline Catheters and Power Pic Solo Catheters).

The above information supports the biocompatibility and safe patient use for the ERBELIFT Flexible Probe. There is minimal to no-risk of adverse biocompatibility concerns from the 5 minute or less contact with the gastrointestinal environment.

Based on the history of safe use of these materials as shown in the firm's compliance assessment, the expert report from Dr. Bill Bradbury and the Cytotoxicity testing (MEM Elution) report, there are no new concerns impacting safety / effectiveness regarding biocompatibility and omission of Sensitization and Irritation tests is justified.

Therefore, the proposed device is substantially equivalent to the predicates in this regard.

IX. Software

N/A - No software

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Product: ERBELIFT™ Hand Pump and Flexible Probe

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Item	Present & Acceptable?	Location in Submission
Electrical Safety	N/A	N/A
Electromagnetic Compatibility	N/A	N/A
Mechanical	YES	Included as part of performance testing - device operated as intended

Consensus Standards

The manufacturer identified the following consensus standards as being used in the design and testing of the device:

STANDARD	DESCRIPTION
AAMI / ANSI / ISO 10993-7:1995	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. [Recognition No. 14-76]
EN 980:1996 + A1:1999 + A2:2001	Graphical Symbols for Use in the Labeling of Medical Devices. [Recognition No. 5-32]
ANSI / AAMI / ISO 10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing. [Recognition No. 2-98]
AAMI / ANSI / ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 1ed. [Recognition No. 14-294]
AAMI / ANSI / ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. [Recognition No. 14-228]
ISO 14971:2007	Medical devices - Application of risk management to medical devices. [Recognition No. 5-40]

XI. Performance Testing – Bench

The firm provided Performance / Animal Testing in **Section III, Page 26** of the original submission. It is a comparative study between the proposed ERBELIFT™ system and the predicate Needle Injection System (K924102) for submucosal elevation (lift) in ex-vivo and in-vivo porcine models. A summary of this testing is provided below:

Purpose:

To determine whether a hand-pump needle-free elevation system will affect procedure time and generate tissue elevation without complication when compared to a needle system.

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Product: ERBELIFT™ Hand Pump and Flexible Probe

Test Method:

A) Ex-Vivo Study

For the ex-vivo study, 10 tissue elevations were performed by 5 endoscopists (2 master clinicians, 2 trainees and 1 novice), using 10 ml of blue-colored normal saline. 5 elevations were performed with the proposed needle-free induction system and 5 with a predicate needle injection system in a porcine stomach model. Each endoscopist was randomly assigned an individual, freshly harvested stomach from a Yorkshire pig (> 25 kg) and the following parameters were measured:

- Flow rate (ml/s),
- Height of elevation (mm)
- Procedure duration (s)
- Perforation rate
- Ease of use (simple, fair, unacceptable)
- Accuracy of elevation placement (within > 3mm, 3mm, < 3mm of intended target)
- Diameter of bleb (2 axis in mm)

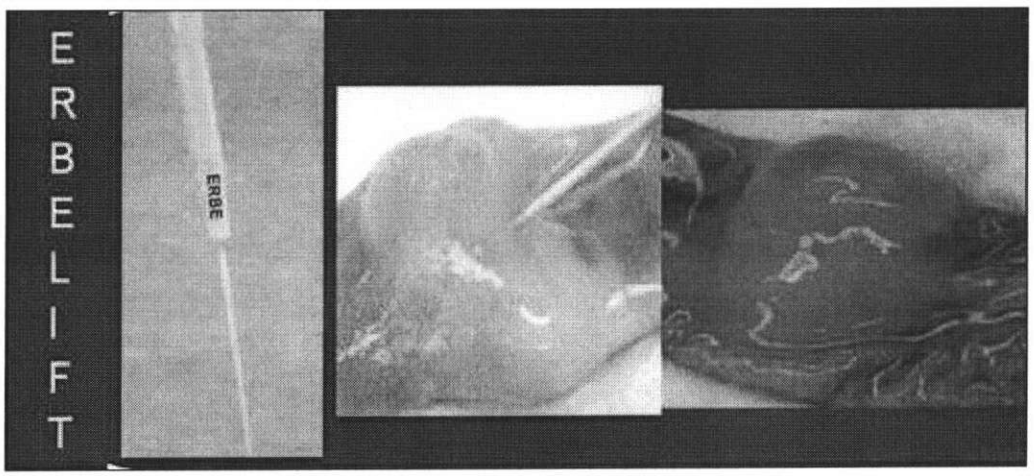

Fig 2.a: Schematic of Ex-vivo study conducted using proposed ERBELIFT system

The above figure displays a schematic of the ex-vivo test conducted using proposed ERBELIFT system. The flexible probe is placed against the mucosa without puncturing it. Once the probe is in place, the handle of the Hand pump is squeezed to deliver a fixed volume of saline into the submucosal polyp bed.

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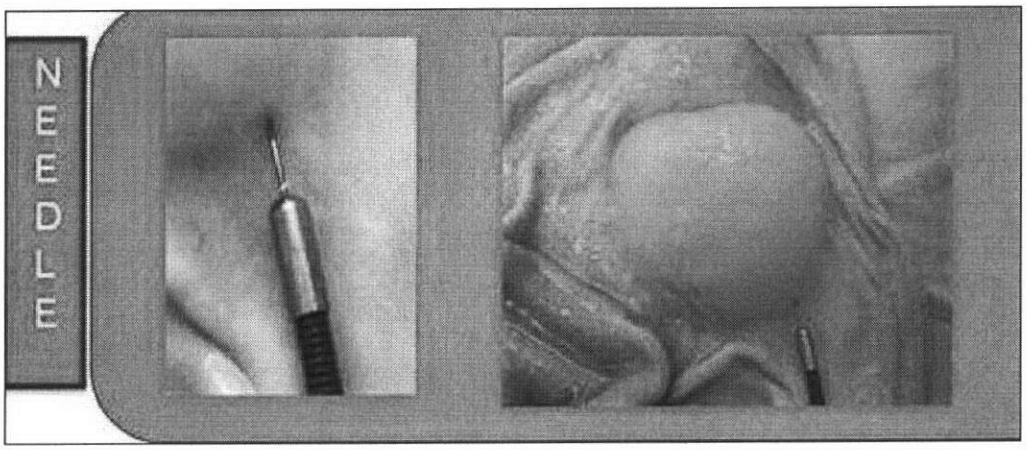

Fig 2.b: Schematic of Ex-vivo study conducted using predicate Carr Locke injection needle system

The above figure displays the schematic of ex-vivo test conducted using predicate needle system. The needle is placed against the target tissue and the mucosa is then punctured by the needle tip to deliver the saline in polyp bed.

Note: The volume (10 ml) of saline for the ex-vivo studies does not reflect the actual amount to be administered for the device use. This volume is selected solely to demonstrate the comparison between the proposed device and the predicate.

B) In Vivo Study

For the in-vivo study, 20 tissue elevations were performed by 3 endoscopists (master clinicians, 1 trainee and 1 novice), using 1.5ml of blue-colored normal saline.

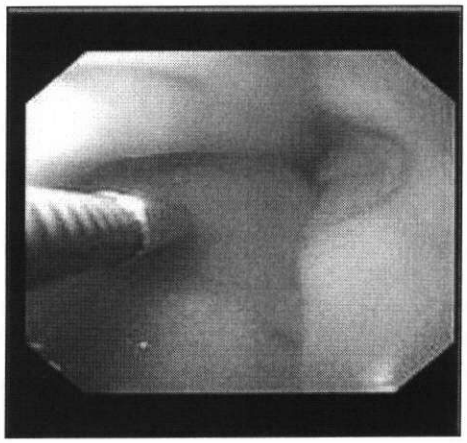

Fig 3.a: Schematic of In-vivo study conducted using the proposed ERBELIFT system

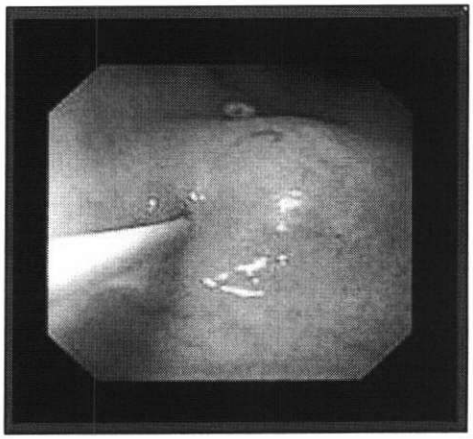

Fig 3.b: Schematic of In-vivo study conducted using predicate Carr Locke injection needle system

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Ten (10) elevations were performed with the proposed needle-free elevation system and 10 with predicate needle injection system in a live porcine model (a >25 kg Yorkshire pig). The following data points were measured:

- Flow rate (ml/s)
- Perforation risk at maximum force

Note: The volume (1.5 ml) of saline for the in-vivo studies does not reflect the actual amount to be administered for the device use. This volume is selected solely to demonstrate the comparison between the proposed device and the predicate.

Results:

The results obtained from the ex-vivo and in-vivo tests are summarized below:

Parameters Tested	Proposed ERBELIFT (Needle Less group)	Predicate Carr Locke (Injection Needle group) K924102	Results / Statistical Analysis
Ex- Vivo Study			
Mucosal lift (independent of the endoscopist skill level)	Accomplished in 100% cases	Accomplished in 92% cases	Mucosal lift was accomplished in greater number of cases, using the proposed device
Perforations	None	-	Testing with the proposed device demonstrated no perforations
Ease of use (Simplicity)	in 92% cases	in 64% cases	$p = 0.02$ proposed device reported comparatively easier / simpler to use
Accuracy	< 3mm in 100% cases	3mm in 76% cases	$p = 0.01$ proposed device reported comparatively accurate
Height of elevation	15.27 ± 4.99 mm	15.84 ± 5.5 mm	$p = 0.72$ hence no statistical difference
Flow rate	0.61 ± 0.09 ml/s	0.53 ± 0.23 ml/s	$p = 0.1$ hence no statistical difference
Total procedure time	19.36 ± 3.35 sec.	28.2 ± 8.85 sec.	$p < 0.01$ use of proposed device resulted in comparatively lower procedure time

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Parameters Tested	Proposed ERBELIFT (Needle Less group)	Predicate Carr Locke (Injection Needle group) K924102	Results / Statistical Analysis
Maximum lift diameter	40.18±10.26 mm	33.03 ± 11.31 mm	p = 0.03 the maximum lift diameter was comparatively higher with the proposed device
In- Vivo Study			
Flow rate	0.39 ± 0.05 ml/s	0.36 ± 0.07 ml/s	p = 0.36 hence no statistical difference
Perforations (at maximum force)*	None	-	Testing with the proposed device demonstrated no perforations

* Based on input from the firm - In the in-vivo study one of the endpoints was "perforation at maximum force". In a discussion with the firm and confirmed by email the firm explained that in the in-vivo study one of the endpoints was "perforation at maximum force". In the conversation, this was defined as the maximum pull / activation force applied to the trigger of the hand pump by the user who is also deliberately ignoring the visual tissue effect – essentially simulating negligent use of the product. The purpose of this endpoint within the in-vivo study was to simulate if a perforation (worst case failure mode) of the tissue could occur when the device is not operated per the intended use - :i.e. if an untrained user, activates the trigger of the hand pump in a negligent manner (quick, strong pull force) in a thin walled tissue area, which does not require a high pull force to achieve a submucosal lift under direct visualization. The results were such that no perforations were caused.

Conclusion / Discussion:

The results show that the proposed needle-free system is comparable to the predicate in terms of flow rate and height of elevation. Also, the wall of the pig lumen is thin as compared to that of humans.

The distended bowel wall has a total thickness of 1.5 mm. Each layer (mucosa, submucosa and muscularis propria) is approx. 0.5 mm thick.

Since the ex-vivo / in-vivo tests showed no perforations in the pigs, there are no new concerns of safety / effectiveness for use in humans. The comparatively thicker lumen wall in the humans will withstand the mechanical force for saline induction with no greater risk of perforations than that of the predicate devise.

Overall, the proposed device functions as intended and there are no new safety or effectiveness concerns from performance standpoint. Therefore, the proposed device is substantially equivalent to the predicate in this regard.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XII. Performance Testing – Animal

The firm provided Animal Testing in Section III, Page 26 of the original submission. Please note that the ex-vivo and in-vivo studies discussed above (section XI of this Review Memo) were conducted on Yorkshire pigs and therefore they are representative of the Animal Testing. As discussed above, there is no impact on the safety or effectiveness of the device.

Therefore, the proposed device is substantially equivalent to the predicate in this regard.

XIII. Performance Testing – Clinical

N/A - No clinical data relied upon to determine substantial equivalence.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See Appendix A1.1 for the Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

   Same indication(s) statement

2. Explain why there is or is not a new effect or safety or effectiveness issue:

   NA

3. Describe the new technological characteristics:

   The new device utilizes "jet injection" technology rather than needle based injection. In the subject device, saline is forced through a blunt tipped probe having a 120 µm inner diameter that is in direct contact with the mucosal tissue, The force to the saline is generated by a hand pump in which a syringe containing saline is loaded. The saline is inducted through the mucosal layer (path of least resistance) into the submucosal tissue where the bleb forms.

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Product: ERBELIFT™ Hand Pump and Flexible Probe

4. Explain how new characteristics could or could not affect safety or effectiveness:

   The new characteristics have the potential to impact both the safety and effectiveness of the device. The safety concerns related to perforation / laceration exist and the device's ability to generate acceptable polyp lift equivalent to that of the predicate is an effectiveness concern.

   To address these concerns the firm provided results from animal testing (ex-vivo and in-vivo testing) to demonstrate equivalent performance of the subject device to the predicate device. The results from the testing, as summarized on page 23 of this review memo, show that the subject device performed equivalently to the predicate and did not result in any tissue perforations or lacerations.

5. Explain how descriptive characteristics are not precise enough:

   NA - Descriptive characteristics are not precise enough to demonstrate that the proposed device can achieve submucosal elevations (polyp lift) comparable to that achieved with predicate needle system and without elevating the risk of perforations.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

   No new safety or effectiveness questions are raised with the change in technology to the subject device as compared to the predicate device. The safety concerns related to perforation / laceration exist and the device's ability to generate acceptable polyp lift equivalent to that of the predicate is an effectiveness concern. These are the same issues that the predicate device presented.

7. Explain why existing scientific methods can not be used:

   NA

8. Explain what performance data is needed:

   Performance / animal data is needed to demonstrate that the proposed device functions as intended and that it does not increase the risk of perforations. The following parameters: accuracy, flow rate, perforation risk, bleb diameter and height of submucosal elevation should be considered.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

   The ex-vivo and in-vivo animal tests demonstrate that the proposed device is comparable to the predicate (K924102) in terms of accuracy, flow rate, perforation risk, bleb diameter and height of submucosal elevation.

   Overall, the performance / animal data demonstrated that the proposed device functions as intended and the change in technological characteristic does not raise new concerns for safety or effectiveness of the device. Therefore, the proposed device is substantially equivalent to the predicate in this regard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-DIDRecords@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XV. Deficiencies

Item		Description of Deficiency
1.	**Location:**	**Missing – Standards Data Report for 510(k)s**
	Finding:	In Section I, Page 6 of your submission you make reference to standards EN 980 and ISO 11607-2. The FDA requires that Form 3654 be included with all 510(k) submissions that reference a national or international standard. A separate form is required for each standard referenced in the 510(k). Please complete the identified form for EN 980 and ISO 11607-2. The form is available on the FDA website at the following link: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf Note: Please reference the amendments (A1:1999 and A2:2001) in the standard title for EN 980.
	Response:	Form 3654 for ISO 14971, EN 980, 11607-02 (That is Standards in Section I, Page 6 in which Forms 3654 were not completed) were not submitted in the 510(k) for the Standards because the Form for these Standards cannot be accurately completed (Note: There is no test data, etc. involved with these standards.). These standards provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively. I have spoken with FDA regarding this matter and was told to use the Form and Summary Report for Standards in applicable situations. As requested amendments (A1:1999 and A2:2001) were included in the standard title for EN 980 on Section I, Page 6. See Exhibit 1.
	Closed Out:	06 Jul 2009 The firm indicated that in previous submissions to the agency, the agency FDA guided them to utilize the 3654 Form and Summary Reports for such standards in "applicable situations" and that the form was not needed for the referenced standards. Based on this, the firm did not include 3654 forms / summary reports for the ISO 14971, EN 980 and ISO 11607-2 standards. Additionally, the firm revised the title for EN 980 to include the amendments (A1:1999 and A2:2001). Section I, Page 6 (CDRH Coversheet) was revised to reflect this change. The response addressed the deficiency. See Item 2, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
2.	**Location:**	**Missing – Summary Reports**
	Finding:	In Section III, Pages 13-15, you have provided FDA Form 3654 for ISO 10993-1, ISO 11135-1 and ISO 10993-7. Per these forms, summary reports are stated to be provided. However, no such reports could be located in the submission. Please provide summary reports for the above mentioned standards to demonstrate the extent of conformance of these standards.
	Response:	A Summary Report was completed as Declaration of Conformance with Consensus Standards for each of the above Standards. See Page III-16 for ISO 10993-1. ISO 11135-1 and ISO 10993-7 are Standards that involve sterilization guidelines (i.e., EO validation and EO residuals). The Declaration of Conformance with Consensus Standards for ISO 11135-1 and ISO 10993-7 Standards were provided on Page III-17. Also, the involved Sterility Information regarding these Standards is provided on Page III-31. In the past, providing the Summary Reports in this manner was acceptable to FDA.
	Closed Out:	06 Jul 2009 The firm clarified the location of declaration of conformance and summary reports for the following standards: ISO 10993-1, ISO 11135-1 and ISO 10993-7. The declaration of conformance for ISO 11135-1 and ISO 10993-7 was provided on Page 17 of Section III of the original submission. A common summary report with Sterility information associated with these standards was provided on Page 31 of Section III of the original submission. Also, the compliance assessment and declaration of conformance for ISO 10993-1 was provided on Page 16 of Section III of the original submission. Additionally, the firm provided the MEM Elution report to demonstrate the Cytotoxicity testing for the proposed Flexible Probe. The response addressed the deficiency. See Item 4, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
3.	**Location:**	**Section III, Page 4 – 510(k) Summary (Conclusions)**
	Finding:	You have stated that the technological characteristics of the proposed ERBELIFT system are 'similar' as compared to the predicates. However, in reviewing the submission the technological characteristics of the proposed needle less system are significantly different as compared to the predicates with needle system. Please update this section to state the technological characteristics as 'different' and provide a revised 510(k) summary.
	Response:	The conclusion was revised. See Exhibit 2. Note: The entire 510(k) Summary was provided in the Exhibit without the "Confidential" identifier so that it could be used for FDA's posting of the 510(k).
	Closed Out:	08 Jul 2009 The firm provided a revised 510(k) summary, without the "Confidential" identifier so that it could be used for FDA's posting of the 510(k). The "Conclusions" section of the summary was modified to identify the technological characteristics of the proposed device as "different" from the predicates. The response addressed the deficiency. See Item 3, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-CRSPATHS@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
4.	**Location:**	**Section III, Page 17 – Declaration of Conformance with Consensus Standards**
	Finding:	You have not listed the consensus standards ISO 14971, EN 980, ISO 11607-2 and ISO 10993-7 in the 'Declaration of Conformance'. However, these standards have been identified in the Utilization of Standards page of the CDRH Cover Sheet (Section I, Page 6). Please provide a revised 'Declaration of Conformance with Consensus Standards' identifying all applicable standards or include rationale as to how the standards are used.
	Response:	ISO 10993-7 was included as a Declaration of Conformance with Consensus Standards on Page III-17. Again, ISO 14971, EN 980, ISO 11607-2 are Standards that provide guidance for risk analysis, using international symbols on labeling, and validating packaging respectively; therefore, Declaration of Conformance with Consensus Standards for these Standards is not applicable.
	Closed Out:	06 Jul 2009 In reviewing the response, the firm clarified that ISO 10993-7 was included in Declaration of Conformance (Section III, Page 17 of the original submission). The additional standards: ISO 14971, EN 980 and ISO 11607-2 provide guidance for risk analysis, using international symbols on labeling, and validating packaging, respectively. Therefore, the firm stated that the Declaration of Conformance for these additional standards is not applicable. See close out comment for Item #1 of this report relating to completion of form 3654 for the additional standards noted. The response addressed the deficiency.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-DIDOMAIL@fda.hhs.gov or call 301-796-8118.
SD1.4.1q (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
5.	**Location:**	**Section III, Page 19 – Biocompatibility Testing**
	Finding:	You have provided a summary of biocompatibility for individual materials of the proposed device. For biocompatibility assessment, FDA recommends that the test articles be extracted from the finished, sterilized device. Also, there may be possible contamination while assembling the device. Please explain as to how the data provided demonstrates the biocompatibility of the finished sterilized device. Alternatively, please provide a revised biocompatibility testing for the final finished device. Per, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the following tests are recommended for the proposed device: Cytotoxicity, Sensitization and Irritation (or Intracutaneous Reactivity). The compliance assessment and the basis provided for individual materials are not adequate to justify the omission of Sensitization and Irritation tests. Please provide a detailed explanation as to how the omission of these tests will not affect the biocompatibility of the finished device. Alternatively, please provide biocompatibility reports for Sensitization and Irritation tests. Please reference the standard* as applicable for specific tests and ensure that all the test reports follow the extent of regulation of respective standard. Also, please include a separate form 3654 for additional standards (if any) that are referenced in the submission. *Per the FDA website, ISO 10993-10 is the recommended biocompatibility standard for irritation and delayed-type hypersensitivity tests. Also, per extent of regulation for ISO 10993-1, ccompliance with FDA Good Laboratory Practices (GLPs) regulation is required. Please revise the biocompatibility section to indicate that the testing is done in accordance with GLP guidelines. Additionally, there are references to the cytotoxicity and biocompatibility risk assessment reports in the submission; however no such reports could be located. Please provide these reports, since they are necessary for assessing biocompatibility. Note: Please revise the Utilization of standards list in the CDRH Coversheet and the Declaration of Conformity to reflect the identification of additional standards.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
Response:	The materials for the Flexible Probe were chosen based upon their long history of biocompatibility as well as their use in medical applications (e.g., many disposable medical instruments, catheters, shunts, etc. use these materials.). Our initial assessment of the need to only perform Cytotoxicity was confirmed by a Biocompatibility Risk Assessment generated by an independent expert (Dr. Bill Bradbury). See Exhibit 3.1. Prototype samples (Note: The entire Flexible Probe) were prepared by our contract manufacturer using the same manufacturing processes that will be employed for the finished medical device. These samples were sent to a contract testing laboratory. The Flexible Probes were sterilized (sterilization representing greater than 2X) and then the Cytotoxicity (MEM Elution) testing was performed. Reactivity was "0" (Note: Sterilization and Testing was done under GLP.). See Exhibit 3.2.
Closed Out:	08 Jul 2009 The compliance assessment for ISO 10993-1 was provided earlier, in Section III, Page 16 of the original submission. Additionally, the firm provided the Biocompatibility Risk Assessment generated by an independent expert (Dr. Bill Bradbury) to address the biocompatibility of the direct / indirect patient contacting materials. The report provided information regarding the long history of their biocompatibility as well as their use in medical applications (e.g., disposable medical instruments, catheters, shunts, etc.). Additionally, the firm provided material specification sheets for all the direct / indirect patient contacting materials (PEEK, Nylon 11, titanium dioxide, Genesolv S-T solution, Colorcon MD-1185 and Colorcon MD-1120). Based on the history of safe use of these materials and the firm's biocompatibility compliance assessment, the omission of Sensitization and Irritation tests is justified. Also, the firm provided MEM elution report to demonstrate the cytotoxicity testing of the Flexible Probe. The results demonstrated that the materials are non cytotoxic. Additionally, the firm stated that the biocompatibility testing was performed on the final finished sterile Flexible Probe and as per GLP guidelines. Therefore, based on the compliance assessment, the expert report from Dr. Bill Bradbury and the cytotoxicity testing (MEM Elution) report, there are no new concerns impacting safety / effectiveness from the biocompatibility standpoint. The response addressed the deficiency. See Items: 4 & 5, Sub-Tab 01Jul2009 and Item 3, Sub-Tab 07Jul2009, Tab 7 of the Review Binder for details.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-PA156@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
6.	**Location:**	**Section III, Page 20 – Materials Used**
	Finding:	Per FDA Guidance Document for the Traditional 510(k) dated August 12, 2005, it is recommended that adequate material information be provided for all the device components that come into direct or indirect contact with the patient. Please provide material designation and manufacturer information for the following materials: Nylon 11 (Clear) and Nylon 11 (White). Also, please clarify the model number of Polyetheretherketone (PEEK) and provide material specifications sheet for the Colorcon MD-1185 and Colorcon MD-1210. Additionally, please identify the K number of the control syringe intended to be used as an accessory with the proposed device.
	Response:	As provided in the biocompatibility study (See Page III-20) , PEEK, Nylon 11 White, Genesolv S-T (Solvent), and Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer) are the materials that have the potential of indirect and/or direct patient contact (Note: Not Nylon Clear). The requested additional material information is as follows: PEEK: Victrex® *PEEK* Type 381G, Natural [Material Safety Data Sheet (MSDS) CAS#31694-16-3 – 381G] {See Exhibit 4.1} Nylon 11 White: Elf Atochem North America Nylon 11 (Clear) [MSDS CAS# - 25587-80-8 - Part # 0096 – Medron] with Whittaker, Clarke, and Daniel Inc. 0.9 wt.% Titanium Dioxide (TiO_2) [MSDS CAS # 13463-67-7] {See Exhibit 4.2} Genesolv ST (Solvent): Honeywell Genesolv S-T [MSDS] {See Exhibit 4.3} Colorcon MD-1185 as well as MD-1210 (Printing Ink and Reducer): Colorcon Black Ink (MD-1185) & Colorcon Reducer (MD-1210) [MSDSs] {See Exhibit 4.4} ***Note: For additional information in regards to materials of the device and as well as indirect and direct patient exposure reference Page IV-5 (Device Drawing), Pages III-18 to III-26 (Biocompatibility Study) and Exhibit 3.1 (Biocompatibility Risk Assessment by Independent Expert Dr. Bill Bradbury)*** Control Syringe: Deroyal; Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings (3 Rings); 510(k) Number K920135

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5716.
SD04-1 (16 Mar 2009) Mandatory

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
	Closed Out:	06 Jul 2009 The firm identified the model number of Polyetheretherketone (PEEK) as Victrex® *PEEK* Type 381G, Natural. Also, the firm provided material specification sheets for the all the direct/ indirect patient contact materials, namely PEEK, Nylon 11, Genesolv S-T solution, Colorcon MD-1185 and Colorcon MD-1120. Additionally, the K number for the control syringe was identified as K920135 (Deroyal;_Part Number (P/N) 77-712391; Control Syringe, 10 ml Male Luer Lock Ring and Finger Rings). The response addressed the deficiency. See Item 5, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
7.	**Location:**	**Missing – Contraindications (Instructions for Use Manual: Proposed Labeling)**
	Finding:	Per labeling provided on Page 4, the use of the predicate K924102 is contraindicated for uncooperative patients and/or patients with severe coagulopathy. Also, as stated on Page 23, the contraindication for the predicate K040961 include those specific to any endoscopic procedure, uncooperative patients, and patients with coagulopathy. In reviewing the Instructions for Use Manual for the proposed device, there are no contraindications provided. Please provide revised labeling with the contraindications included or provide a rationale explaining why you feel the contraindications are not applicable to your device.
	Response:	The statement, "Contraindications: The use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy.", was added to the labeling (Instructions For Use). See Exhibit 5.
	Closed Out:	06 Jul 2009 The firm provided revised Instructions for Use manual, including the following contraindication: "the use of these devices is contraindicated for uncooperative patients and/or patients with severe coagulopathy." The response addressed the deficiency. See Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-ECTRACS@fda.hhs.gov or call 301-796-8118.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
8.	**Location:**	**Section V, Pages 32 – Safety Precautions / Warnings**
	Finding:	The predicate labeling provided for comparison contains precautions / warnings specific to endoscopic procedures and handling of the device. However, the proposed labeling does not include these warnings / precautions. Since, the proposed device employs a comparable endoscopic procedure (except for needle injection), please revise the labeling to include relevant warnings / precautions.
	Response:	I have meticulously reviewed the "Warnings and Precautions" in the labeling of the predicates for statements which are applicable in our labeling. I find that I have included all necessary statements as "Safety Instructions- Warnings" as follows: Training, not using damaged product, not using product in which there may be a package integrity issue, not using product beyond its expiration, etc. (Note: All of these statements were considered as a result of our risk assessment.). Many statements in the "Warnings and Precautions" for the predicate devices actually do not belong in the section (e.g., the device being single use, compatibility of working channel scope size, solution types, etc.). The information is instructional in nature and diminishes the effectiveness of the "real" Warnings and Precautions in the predicate labeling. Therefore, as directed by FDA, some of the statements in the predicate labeling Warnings and Precautions section are included in our labeling but not in our "Safety Instructions- Warnings" section.
	Closed Out:	06 Jul 2009 In reviewing the response, the safety warnings and precautions, as applicable for any endoscopic procedure, were incorporated in the Instructions for use manual. They have not been discussed in a separate section. Instead, they are included within the directions for use of the proposed device. The response addressed the deficiency.

So

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
9.	**Location:**	**Section V, Pages: 34 & 35 – Marketing Statements / Claims**
	Finding:	The marketing statements / claims for the proposed device state: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe, especially with wet gloves. The information provided in the submission does not support any of the above mentioned claims. Please remove these claims or provide scientific explanation to substantiate them. Please note that claims of this nature typically require clinical data for substantiation. If such data is needed, the device will not be eligible for 3rd Party Review and will need to be withdrawn and submitted directly to FDA. Also, on Page 35, you claim that "in larger working channel scopes, the Probe may be able to be passed down alongside another instrument." Please provide a scientific discussion and supporting information as to how the integrity of the probe will remain unaffected with the presence of another instrument within the working channel. Alternatively, please remove this claim and revise the section.
	Response:	Substantiation of Claim: "***An easier and less demanding method of generating force to drive the fluid into the submucosa.***" Pulling the trigger of the ERBELIFT Hand Pump ergonomically designed pistol grip hand pump allows for less activation force to push the plunger of the syringe compared to an in-line motion like when the user uses their hand force applied to syringe connected to an injection needle. Substantiation of Claim: "***Flexible Probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe.***" The winged luer lock on the ERBELIFT Flexible Probe provides more surface area for the user's fingers to grasp onto when twisting the luer to lock or unlock – this additional winged surface area is not available on standard leur locks used on the injection needles. Note: "***especially with wet gloves***" was removed from the statement. See Exhibit 6. **"In larger working channel scopes, the Probe may be able to be passed down alongside another instrument."** was removed from the list. See Exhibit 6.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item		Description of Deficiency
	Closed Out:	06 Jul 2009 The firm provided adequate information to substantiate the following marketing statements / claims: • An easier and less demanding method of generating force to drive the fluid into the sub mucosa • Flexible probe – connecting hub with standard luer lock that is winged which allows easy connection to the syringe (Note: the phrase "especially with wet gloves" was removed from the statement) Also, the claim "In larger working channel scopes, the Probe may be able to be passed down alongside another instrument" was removed from the submission. The response addressed the deficiency. See Item 6, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
10.	**Location:**	Throughout Submission - Classification Identification
	Finding:	The classification for the device is identified as 876.1500 (FBK) and / or 880.5430 (KZE). Please revise all documents (e.g. CDRH cover sheet, summary, etc.) to identify the classification as the 876.1500 (FBK) or revise to include both classifications and a detailed discussion supporting the classification designation.
	Response:	All documents in the submission were changed to identify the device's classification as only 876.1500 (FBK). See Exhibit 7 (Also Exhibit 2).
	Closed Out:	08 Jul 2009 The firm identified the proposed device classification as 876.1500 (FBK) and revised the affected pages (of the CDRH Coversheet, Form 3674 and submission summary) to reflect this change. The response addressed the deficiency. See Item 7, Sub-Tab 01Jul2009, Tab 7 of the Review Binder for details.
END		

XVI. Contact History

See Appendix A1.2 for copies correspondence between third party and the firm.

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Records processed under FOIA Request #2011-1893, Released by CDRH on 09-20-2012.

Intertek

Intertek Project Number: 3179301

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

XVII. Recommendation

Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscopic Injector Needle, Gastroenterology / Injector, Fluid, Non-Electrically Powered
Regulatory Class:	II
Product Code:	FBK

Primary Third Party Reviewer:

Daniel W. Lehtonen — 28 SEP 2009
Sr. Staff Engineer - Medical Devices — Date

Responsible Third Party Official:

Jay Y. Kogoma — 28 Sep 2009
Sr. Staff Engineer - Medical Devices — Date

Branch Chief — Date

The following Appendices are attached to this review memo

SE Flowchart ..... Appendix A1.1
Written Communications in Reverse Chronological Order ..... Appendix A1.2
Firm's Response, Protocols and Results ..... Appendix A1.3

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118

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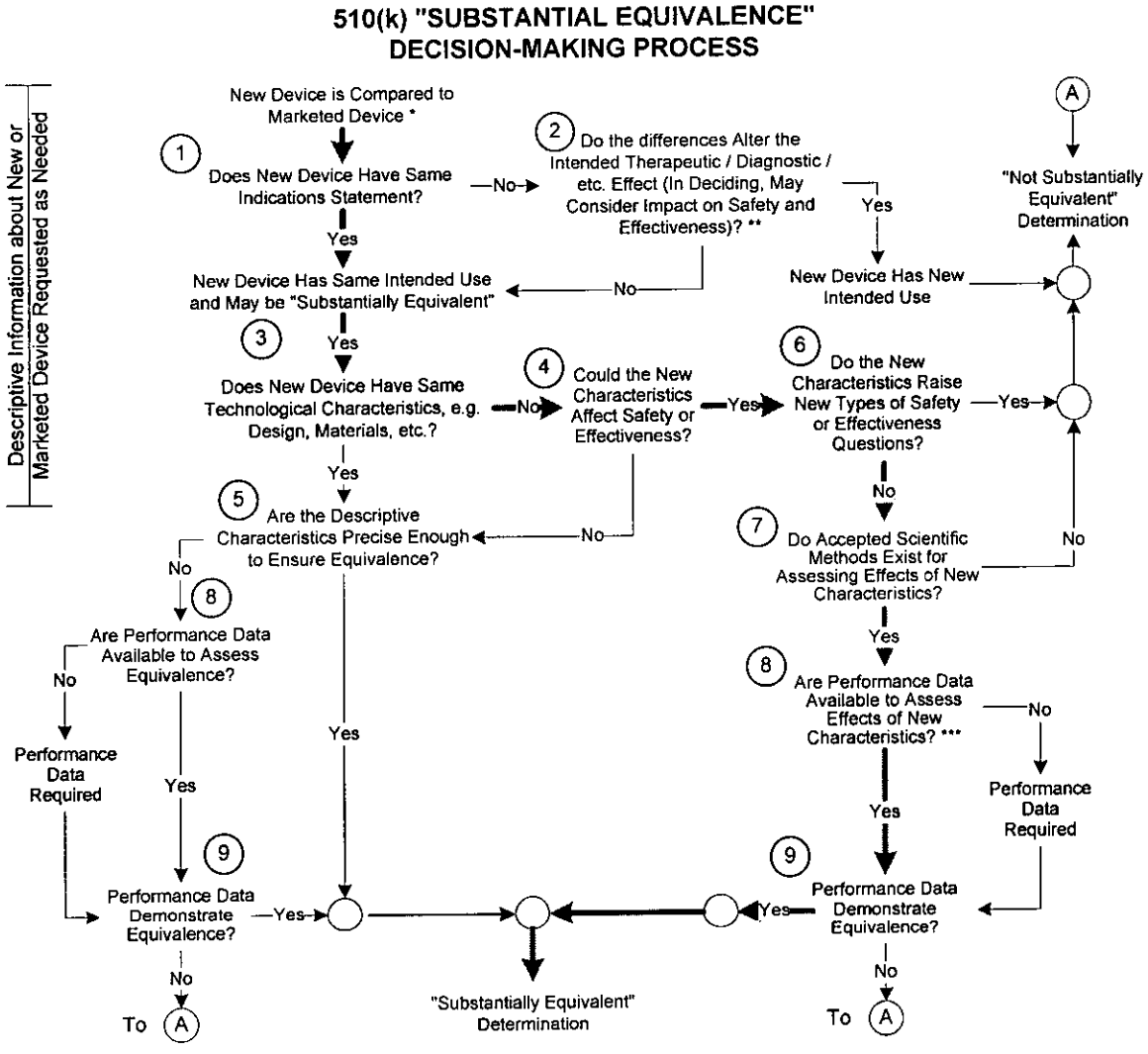
Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Appendix A1.1

SE Flowchart



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post Amendments) device is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Appendix A1.2

Written Communications in Reverse Chronological Order (since original submission to FDA)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

SD1.4.1q (16 Mar 2009) Mandatory

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Dan Lehtonen Intertek
Sent: Tuesday, September 01, 2009 9:35 AM
To: 'John Tartal'
Cc: Erica Matthes
Subject: RE: Response to FDA's Questions involving ERBELIFT

Hi John,

I received 2 emails with attachments. I am out of the office today, but will be back Wednesday morning. I will look through the response and then give you a call if there are any questions.

Thanks,

Dan

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Fax: 330-405-5518
E-mail: dan.lehtonen@intertek.com

www.intertek.com

From: John Tartal [mailto:john.tartal@erbe-usa.com]
Sent: Monday, August 31, 2009 5:19 PM
To: John Tartal; Dan Lehtonen Intertek
Cc: Nicole Bartolozzi Intertek; Erica Matthes
Subject: RE: Response to FDA's Questions involving ERBELIFT

Per my voice mail can you let me know that you got E-Mails. We will be following up with you to discuss further.

From: John Tartal
Sent: Monday, August 31, 2009 3:53 PM
To: 'dan.lehtonen@intertek.com'
Subject: FW: Response to FDA's Questions involving ERBELIFT

First one didn't go through so I'm resending.

From: John Tartal
Sent: Monday, August 31, 2009 3:48 PM
To: 'Dan Lehtonen Intertek '
Cc: Erica Matthes
Subject: Response to FDA's Questions involving ERBELIFT

Dear Dan,

See attached draft response with Exhibits 1 to 3 to FDA's questions. Please forward this information to Agency. If it doesn't adequately address the issues, we would like to have

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

phone conversation with her to clarify any concerns (Note: Our Product Manager and Dr. Carr-Lock who were involved in the testing will be able to support the work that was performed.).

Note: Exhibits 4 and 5 to follow in the next E-Mail.

John Tartal
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Tel: 770/955-4400 x 133
Fax: 770/955-2577
E-mail: John.Tartal@erbe-usa.com
Web: www.erbe-usa.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Monday, August 31, 2009 5:19 PM
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Note: Exhibits 4 and 5 to follow in the next E-Mail.

John Tartal
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Tel: 770/955-4400 x 133
Fax: 770/955-2577
E-mail: John.Tartal@erbe-usa.com
Web: www.erbe-usa.com

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Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Monday, August 31, 2009 3:54 PM
To: Dan Lehtonen Intertek
Subject: FW: Response to FDA's Questions involving ERBELIFT Continued
Attachments: Exhibits 4 and 5.pdf

Resending

From: John Tartal
Sent: Monday, August 31, 2009 3:48 PM
To: 'Dan Lehtonen Intertek '
Cc: Erica Matthes
Subject: Response to FDA's Questions involving ERBELIFT Continued

Dear Dan,

Exhibits 4 and 5 to for previous E-Mail.

John Tartal
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Tel: 770/955-4400 x 133
Fax: 770/955-2577
E-mail: John.Tartal@erbe-usa.com
Web: www.erbe-usa.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: John Tartal [john.tartal@erbe-usa.com]
Sent: Monday, August 31, 2009 3:53 PM
To: Dan Lehtonen Intertek
Subject: FW: Response to FDA's Questions involving ERBELIFT
Attachments: 082809 Draft Response to Address Request for Additional Information (Final Draft).docx; Exhibits 1 to 3.pdf

First one didn't go through so I'm resending.

From: John Tartal
Sent: Monday, August 31, 2009 3:48 PM
To: 'Dan Lehtonen Intertek '
Cc: Erica Matthes
Subject: Response to FDA's Questions involving ERBELIFT

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Note: Exhibits 4 and 5 to follow in the next E-Mail.

John Tartal
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Tel: 770/955-4400 x 133
Fax: 770/955-2577
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Dan Lehtonen Intertek
Sent: Thursday, August 06, 2009 8:32 AM
To: Chris Hierholzer
Cc: 'John Tartal'; Erica Matthes
Subject: 3179301 ERBE Lift Update
Importance: High
Attachments: 3179301__FDA_RAI1.doc

Hi Chris,

FDA has asked three questions about the submission. I have reviewed the request and believe that the information needs to be provided as the information does not currently appear to be in the submission.

If after reviewing the content of this report there are questions, please contact me via e-mail at dan.lehtonen@intertek.com, phone at (937) 313-7454, or fax at (330) 405-5518. Additionally, after you have had an opportunity to review the findings, and determine an approximate date that I should expect your response, please let me know so that your responses may be scheduled for review.

Please note FDA **requires** a response within 30 days of hold date identified above. The response can be complete information or a request for an extension. If you need to file for an extension please send the request letter to me and Intertek will submit on your behalf. The maximum period for an extension is 180 days.

Regards,

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Phone: 937-313-7454

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Fax: 330-405-5518
E-mail: dan.lehtonen@intertek.com

www.intertek.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Telephone: +1 330-405-3552
Facsimile: +1 330-405-5518
www.intertek-etlsemko.com

05 Aug 2009

Mr. Chris Hierholzer
Byrne Medical, Inc.
3150 Pollok Drive
Conroe, TX 77303

SUBJECT: FDA Request for Additional Information

Device Name	ERBELIFT™ Hand Pump and Flexible Probe
Intertek Project No.	3179301
K Number	K092090
Date put on Hold	03 Aug 2009

The FDA has reviewed the 510(k) premarket submission for the ERBELIFT™ Hand Pump and Flexible Probe and has requested the information on the following pages.

Please cut and paste the table beginning on the following page into a document that you create on your letterhead and insert your responses to the requests in the identified area of the table. Using this format will simplify the review of the information that you provide.

This is the final report and serves to provide a complete list of items that FDA is requesting additional information for at this time. A written response is required for all items identified.

If after reviewing the content of this report there are questions, please contact me via e-mail at dan.lehtonen@intertek.com, phone at (937) 313-7454, or fax at (330) 405-5518. Additionally, after you have had an opportunity to review the findings, and determine an approximate date that we should expect your response, please let me know so that your responses may be scheduled for review.

Please note FDA **requires** a response within 30 days of hold date identified above. The response can be complete information or a request for an extension. If you need to file for an extension please send the request letter to me and Intertek will submit on your behalf. The maximum period for an extension is 180 days.

Please reference the project number when replying.

Yours sincerely,

Daniel W. Lehtonen

Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices

CC: John Tarttal, ERBE
Erica Matthes, ERBE
Bhavesh Sheth, Intertek

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RAI Request (18 Nov 2007) Mandatory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
1. **FDA Finding:**	The submission identifies predicate devices within the KZE (Non-electrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.
Response:	
2. **FDA Finding:**	The submission references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.
Response:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Item	Description of Deficiency
3. FDA Finding:	The submission references the maximum pressure delivered by the subject device as 650 psi. However, the submission does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids; however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4 of the submission) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information: A. how the determination of less trauma was ascertained B. the amount of pressure generated by the device compared to the amount of pressure generated by hand on the syringe C. the expected penetration distance in different tissues under maximum pressure and D. the method used to ensure that the pressure generated does not exceed 650 psi
Response:	
END	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Cornelius, Mary Jo [Mary.Cornelius@fda.hhs.gov]
Sent: Wednesday, July 29, 2009 11:56 AM
To: jay.kogoma@intertec.com; Dan Lehtonen Intertek
Cc: Janda, Michel D
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe
Importance: High

Dear Mr. Kogoma,
I inadvertently sent you an abbreviated list of deficiencies. To correct this, I am sending a more detailed version that I believe will be more helpful to you.

After reviewing your third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, it appears that addition information is required. The following information is necessary to continue the review of this 510(k).

1. Your review memo identifies predicate devices within the KZE (Nonelectrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.

2. Your review memo references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. However, the submission appears to lack the complete reports for this testing. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. Please ask the sponsor to provide the test protocols and results for these animal studies. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use.

3. Your review memo references the maximum pressure delivered by the subject device as 650 psi. However, your memo does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids, however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

A. how the determination of less trauma was ascertained;
B. the amount of pressure generated by the device compared to the amount of pressure generated by hand on the syringe;
C. the expected penetration distance in different tissues under maximum pressure; and
D. the method used to ensure that the pressure generated does not exceed 650 psi.

As per this email, K092090 has been placed on hold until further correspondence is received. Please note that these deficiencies should not be considered as comprehensive as additional questions may arise during the review of the sponsor's response and your review memo.

Please feel free to contact me if you need clarification regarding these deficiencies. Hard copies of your response are required and can be directed to the FDA document center. Thank you.

Mary J. Cornelius, RN, BSN, CGRN
9200 Corporate Blvd.
Rockville, MD 20850
Email: mary.cornelius@fda.hhs.gov.
Phone: 240-276-4135
Fax: 240-276-4156

NEW after August 1, 2009

Mary J. Cornelius, RN, BSN, CGRN
WO66 RM 0204GH HFZ
10903 New Hampshire
Silver Spring, MD 20993
Email: mary.cornelius@fda.hhs.gov.
Phone: 301-796-6550

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Dan Lehtonen Intertek

From: Cornelius, Mary Jo [Mary.Cornelius@fda.hhs.gov]
Sent: Wednesday, July 29, 2009 11:02 AM
To: jay.kogma@intertek.com; Dan Lehtonen Intertek
Cc: Janda, Michel D
Subject: K092090 ERBELIFT Hand Pump and Flexible Probe
Importance: High

Dear Mr. Kogma,

After reviewing your third party review memo and the submission for the ERBELIFT Hand Pump and Flexible Probe, it appears that addition information is required. The following information is necessary to continue the review of this 510(k).

1. Please provide a copy of the protocol(s) for the Ex- Vivo and In-vivo Studies. The results of these studies are not sufficiently detailed to make an evaluation.

2. In section III, p4 you indicate that amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. Please provide the following information:

   A. how the determination of less trauma was ascertained;

   B. amount of pressure generated by the ERBELIFT Hand Pump compared to the amount of pressure generated by hand on the syringe;

   C. provide upper limit of pressure which results in perforation; and

   D. method used to ensure that pressure generated does not exceed 650 psi maximum listed.

As per this email, K092090 has been placed on hold until further correspondence is received. Please note that these deficiencies should not be considered as comprehensive as additional questions may arise during the review of the sponsor's response and your review memo.

Please feel free to contact me if you need clarification regarding these deficiencies. Hard copies of your response are required and can be directed to the FDA document center.

Thank you.
mjc

Mary J. Cornelius, RN, BSN, CGRN
9200 Corporate Blvd.
Rockville, MD 20850
Email: mary.cornelius@fda.hhs.gov.
Phone: 240-276-4135
Fax: 240-276-4156
NEW after August 1, 2009
Mary J. Cornelius, RN, BSN, CGRN
WO66 RM 0204 G/H
10903 New Hampshire
Silver Spring, MD 20993
Email: mary.cornelius@fda.hhs.gov.
Phone: 301-796-6550

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012

Sponsor: Byrne Medical, Inc.

Product: ERBELIFT™ Hand Pump and Flexible Probe

Appendix A1.3

Firm's Response, Protocols and Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

August 28, 2009

Intertek
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087
Attn: Daniel W. Lehtonen,
Senior Staff Engineer – Medical Devices

Intertek Project No.: 3179301, 510(k): K092090 – ERBELIFT™ Hand Pump and Flexible Probe

Additional information was requested regarding the above Project/510(k) through a request for Additional Information dated 08/05/09 and E-Mailed on 08/06/09. To facilitate the review, the questions with our responses are included in the table with additions as part of Exhibits. We have included one complete paper copy and one electronic copy. Please accept this material into the record for the Project/510(k).

We believe that the response enclosed has adequately resolved the request as noted. However, if you have any further questions or need technical assistance, please call John Tartal at (770) 955-4400 or email direct at "John.Tartal@erbe-usa.com".

Sincerely,

Chris Hierholzer
Quality Control Manager
Byrne Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request # 2012-0896, Released by CDRH on 09-20-2012.

Item		Description of Deficiency
1.	**FDA Finding:**	The submission identifies predicate devices within the KZE (Non-electrically powered fluid injector) and FBK (Endoscopic injection needle) product codes. As the subject device incorporates technologies and indications from both product groups, all relevant recognized consensus standards also apply to the subject device. The KZE product code identifies ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods as a recognized consensus standard. In addition, the FBK product code identifies ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes as a recognized consensus standard. Please ask the 510(k) sponsor to demonstrate compliance with these recognized consensus standards as appropriate.
1.	**Response:**	Along with the two (2) recognized consensus standards stated, many other standards were considered. Each standard was carefully evaluated for the appropriateness/relevance with the ERBELIFT™ Hand Pump and Flexible Probe. Both of the stated standards were determined not to be applicable as follows: A. ISO 21649:2006 Needle-free injectors for medical use -- Requirements and test methods In the "Introduction" of the standard and a consistent theme throughout the standard is its application "to needle free injectors to administer medicinal products". The primary concern and testing referenced in the standard involves dosages (i.e. intended, ejected, maximum/minimum, etc.). These issues are not applicable to our product as with the predicate (i.e., sterile normal saline used when being introduced into the submucosa for lifting polyps and other lesions under direct visualization through an endoscope.). The ERBELIFT™ Hand Pump and Flexible Probe are used to provide an effect (i.e. lifting/cushioning) and not to deliver medicine. The Hand Pump is not a "Jet" injector as classified in product code KZE. There is no static force mechanism within the device (e.g. there is no spring loaded, CO_2 or pneumatically driven, etc. force.). A squeeze of the Pump's handle makes it easier for a clinician to move a syringe plunger a fixed distance as compared to manually pushing a plunger of the syringe. In both the predicates' and the proposed device, force is applied to the plunger in order to move fluid via a lumen into the submucosa. B. ASTM F1992-99(2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes The scope of this standard involves reusable, heat-stable endoscopic accessory instruments (EAI) designed to be inserted into flexible endoscopes. The ERBELIFT™ Hand Pump is reusable, but it is not intended to be inserted into a scope, nor could it be. (Note: As with mechanical endoscopic lavage pumps which are 510(k) exempt, it is to be cleaned/disinfected with a hospital grade disinfectant. The Pump does not come in contact with the patient or the fluid pathway.) The ERBELIFT™ Flexible Probe is inserted into the endoscope. It is single use and disposable. The other involved accessories (syringe and sterile normal saline) are single use and disposable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Electronic Processed Under FOIA Request #2012-0896, Released by CDRH on 01-20-2012.

Item		Description of Deficiency
2.	**FDA Finding:**	The submission references In-vitro and In-vivo animal testing to support the recommendation of substantial equivalence. A. However, the submission appears to lack the complete reports for this testing. B. Further, the summary information provided in the submission does not appear to include adequate information to reach a meaningful conclusion regarding the performance of the subject device. C. Please ask the sponsor to provide the test protocols and results for these animal studies. D. Please review these complete documents and modify your review memo to comment on the protocols, predetermined acceptance criteria, results, and conclusion reached from this testing. E. Please note that additional expertise may be required to comment on the applicability of the animal model to the proposed indications for use. Note: For clarity purposes, the item was separated into five (5) parts so that each could be addressed.
2.	**Response:**	The concept, product design, testing, etc. of the ERBELIFT™ Hand Pump and Probe followed design control requirements. Included are the following Exhibits of the work performed to support the efficacy and safety of the proposed device: Exhibit 1, Rationale to Support Substantial Equivalence Summary: A rationale to determine the specific aims, goals, methodology, and acceptance criteria for the ERBELIFT™ Performance Testing (specifically, Ex-Vivo and In-Vivo testing) was developed in order to support substantial equivalence. Exhibit 2, ERBELIFT™ Performance Test Plan (Note: Results/Conclusions are Included) Summary: The test plan was devised in collaboration with Dr. David Carr-Locke, Director, The Endoscopy Institute, Brigham and Women's Hospital, Harvard Medical School, Boston, MA. Based upon the rationale, the test plan provides the strategy and the relationship between the specific goals and aims of the individual test protocols and reports used to support substantial equivalence to the predicate. Regarding the evaluation process of ERBELIFT™ per Dr. Carr-Locke: *"For the development of EMR devices, it is well-established in the research and clinical fields within gastroenterology that the response of porcine gastrointestinal mucosa, submucosal and muscularis propria to fluid injection, manipulation and resection accurately reflect the behavior of human tissue to these same procedures."* Two of the specific goals/aims were: 1. Effectiveness of creating a submucosal elevation/lift under direct endoscopic visualization, 2. Performance outputs comparable to an injection needle in the Ex-Vivo testing using porcine stomach and In-Vivo testing in porcine colon.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Electronic Processed Under FOIA Request K2012-0395, Released by CDRH on 01-27-2012

Item		Description of Deficiency
2.	**Response Continued:**	Exhibit 3, Testing Report (Results) of Feasibility Protocol, Ex-Vivo Trial 1 Summary: An evaluation of the technical feasibility of a needle-less method to create a submucosal elevation/lift using the ERBELIFT™ Hand Pump and Flexible Probe. Exhibit 4, Study Protocol and Report, Ex-Vivo Trial 2 Summary: An evaluation to have the most optimal technique (method) to create a submucosal elevation/lift using the ERBELIFT™ Hand Pump and Flexible Probe compared to the standard injection needle method. Exhibit 5, Testing Protocol and Report, In-Vivo Trial Summary: An evaluation of the performance outputs of the ERBELIFT™ Hand Pump and Flexible Probe compared to the standard injection needle. Support to address each part of Question 2 is as follows: A. In reference to complete reports for this testing, a summary of the testing was provided in the initial submission. See summary of Results of each Trial in Exhibit 2 and Protocols as applicable and Reports in Exhibits 3, 4, and 5. B. Regarding the performance of the subject device, please see summary of Results of each Trial in Exhibit 2. C. In response to test protocols and test results for the animals, see Exhibits 3, 4, and 5. D. Specific to your comments about our review memo, as the result of the three (3) phases of testing, it was concluded that: 1) The ERBELIFT™ Hand Pump and Flexible Probe were effective in creating a submucosal elevation/lift under direct endoscopic visualization. 2) The performance of the ERBELIFT™ Hand Pump and Flexible Probe was comparable to an injection needle. 3) No additional safety concerns were raised with using the ERBELIFT™ Hand Pump and Flexible Probe. If further explanation of this process and its applicability to clinically-approved methodology is required, Dr Carr-Locke is willing, as one of the authors of the Ex-Vivo and In-Vivo Performance Test Protocols, to provide additional information, expertise, and discussion. E. Regarding additional expertise required, please see comment above in D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Electronic Processed under FOIA Request 2012-0891, Released by CDRH on 08-27-2012.

Item		Description of Deficiency
3.	**FDA Finding:**	The submission references the maximum pressure delivered by the subject device as 650 psi. However, the submission does not appear to include an analysis of the safety of this pressure setting nor does it compare this pressure to a predicate device. As such, it is unclear why a maximum pressure of 650 psi is indicated. Increased pressures may be indicated for more viscous fluids; however, this contradicts the device's proposed indications for use (saline injection). Please ask the sponsor to provide rationale to support this maximum pressure. Please modify your review memo to include an analysis of the worst case scenario (maximum pressure and minimal tissue thickness / resistance). Further, Section III (pg 4 of the submission) indicates that the amplified fluid force using the ERBELIFT hand pump was less traumatic than the mechanical pressure of a needle with less fluid pressure. It is unclear how this conclusion was reached. Please ask the sponsor to provide the following information: A. how the determination of less trauma was ascertained B. the amount of pressure generated by the device compared to the amount of pressure generated by hand on the syringe C. the expected penetration distance in different tissues under maximum pressure and D. the method used to ensure that the pressure generated does not exceed 650 psi
3.	**Response:**	The submission referenced a maximum pressure delivered by the subject device as 650 psi, however, this value was only a theoretical maximum pressure limit which was not attainable in practice independent of the force applied to the ERBELIFT™ Hand Pump by the individual test subjects (please see Exhibit 3). The Technical Feasibility Study was carefully designed and included flow rate and pressure monitoring for both the subject and predicate devices in order to ascertain and compare the operating pressures associated with the predicate device under normal use. In addition, we were also able to determine the minimum flow rate and pressure (used to measure force) required to breach the mucosa with the saline stream. Unlike when manual pressure or force is applied to the predicate device in order to breech the mucosa, once the minimum flow rate is achieved to breech the mucosa with the subject device, the water stream slows very rapidly (please reference Exhibit 1 for a detailed overview of the procedure). Our experimental study design did include "worst-case scenario testing" (quick hard trigger pulls in order to achieve the highest flow rates during in-vivo testing in pig colon- thinnest wall anatomy). In summary, the subject tissues were excised and a leak test was performed in order to detect perforations. No perforations were detected (For a detailed summary, please see Exhibit 5). The answer to the subset questions are: A. The ERBELIFT™ Hand Pump and Flexible Probe is less traumatic to tissue because: i. A small fluid stream from the tip of the probe pierces the mucosa as compared to a larger stainless steel needle of the predicate. ii. The fluid stream delivered by the subject device is 0.120 mm as compared to a needle tip's outer diameter which is approximately four (4) times larger (0.508 mm). Trauma can be associated with the size of the tissue defect. iii. The fluid delivered is incrementally controlled (i.e. a maximum 0.75 ml is delivered per pull) with the Hand Pump.

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Item		Description of Deficiency
3.	**Response Continued:**	B. While similar pressures and flow rates can be achieved with the subject and predicate devices, the variability in pressure that can be generated by pushing on the syringe plunger depends upon the individual operator. When the trigger of the Hand Pump is squeezed faster, the flow rates and pressures increase just like when the plunger is manually pushed harder with predicate devices. The key here is that with both the proposed and predicate devices, lifting is performed under direct visualization. Regarding comparison of flow rates and pressures, see Exhibit 3. C. Unlike the predicate needle device which uses a solid needle to "blindly" find the submucosal tissue plane (by trial and error, please see Exhibit 1), a **minimum** pressure or fluid flow rate is utilized to penetrate the mucosa with the subject device. As soon the fluid stream comes in contact with resistance (i.e.-tissue, fluid collection in the submucosa), the fluid continues to follow the path of least resistance and collect in the submucosa. Our "worst case scenario testing" failed to perforate even the thinnest wall anatomy in an in-vivo environment meaning only a mucosal breech was possible. D. There are several factors which influence maximum pressure. The size of the orifice, diameter of the syringe, length of the device or flow channel, etc... For example, a smaller orifice and or smaller diameter syringe or both would lead to extremely high pressures; however, the flow rate may be so low that it does not provide the desired tissue effect. Except for the differences between individual operators (cannot be controlled with the predicate device), the mechanical drive, orifice size, syringe, and probe limit the maximum flow rate. Both the predicate and subject devices operate with very similar flow rate variability.

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Exhibit 1, Rationale to Support Substantial Equivalence

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ERBE
USA INCORPORATED
Surgical Systems

Rationale to Support Substantial Equivelance:

ERBELIFT™ System (Proposed)
to
Injection Needle (Predicate)

WRITTEN BY: **Erica Matthes**
Technical Product Manager, ERBE USA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The rationale behind the specific aims, goals, methodology and conclusions used for the ERBELIFT Performance Testing (ex-vivo and in-vivo) to support substantial equivalence is best explained by:

First. Reviewing current clinical practice, treatment objectives, techniques, technical requirements, limitations and desired improvements for the universally marketed predicate device (injection needle) and its intended use – *supported by peer reviewed publications and thought leader opinion*

Second. How and why new endoscopic devices, methods and/or techniques are evaluated by physicians prior to clinical use – *see statement from Dr. David Carr-Locke and peer review publications*

Third. Relating such to the technological characteristics, methodology and performance requirements (technical and clinical) evaluated herein to prove substantial equivalence** for the device in question (ERBELIFT system)

***Substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards, and other characteristics, as applicable.*[1]

The following will expand on the 3 steps above, with more detail and supportive documentation:

1. *Established Clinical Method of Practice Review - Injection Needle (Predicate Device):*

The following discussion summarizes the clinical methods of practice, treatment objective, and associated technology for the predicate (injection needle) - established by medical leaders in the fields of Gastroenterology and Gastrointestinal Endoscopy, and supported by the associated published citations.

Endoscopic Mucosal Resection (EMR) is an endoscopic technique developed for removal of lesions confined to the superficial layers (mucosa and submucosa) of the GI tract. Injection-assisted EMR, also often called "Saline Assisted Polypectomy" or "Injection Assisted Endoscopic Mucosal Resection (EMR)" is frequently used for large flat colon polyps. This technique was first introduced in 1955 for rigid sigmoidoscopy and then in 1973 for flexible colonoscopy[2].

In the colon and rectum, EMR is widely performed using the simple snare resection technique. The colon wall is 1.5–2.2 mm in total thickness, and thermal damage to deep layers of the colon is frequently encountered.[3]

Submucosal injection to lift the lesion before snare resection is needed to try to avoid complications and improve the technical feasibility of the procedure[4]. See Figure 1 on following page.

- The procedure starts with the injection of saline through a long flexible endoscopic needle, into the submucosal space under the lesion, creating a "safety cushion."
- The cushion lifts the lesion, thereby increasing the distance between the base of the lesion and the serosa / muscle layer.

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[1] FDA Device Regulation and Guidance: "*Premarket Notification (510k) - What Is Substantial Equivalence*", http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#se

[2] Sergey V. Kantsevoy, et al. Prepared by: ASGE TECHNOLOGY COMMITTEE. *Endoscopic mucosal resection and endoscopic submucosal dissection. Gastrointestinal Endoscopy.* July 2008 (Vol. 68, Issue 1, Pages 11-18)

[3] Tsuga, K, Haruma, K & Fujimura, J et al. *Evaluation of the colorectal wall in normal subjects and patients with ulcerative colitis using an ultrasonic catheter probe.* Gastrointest Endosc 1998; 48: 477–84.

[4] Soetikno RM, Gotoda T, Nakanishi Y, et al. *Endoscopic mucosal resection.* Gastrointest Endosc 2003;57:567-79.

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- When current is then applied via a polypectomy snare, the lesion can be more safely removed because of a large submucosal 'cushion' of fluid which lessens the likelihood of thermal injury to the deeper layers of the colon wall (i.e.: muscularis propria, serosal surface).[5,6,7]

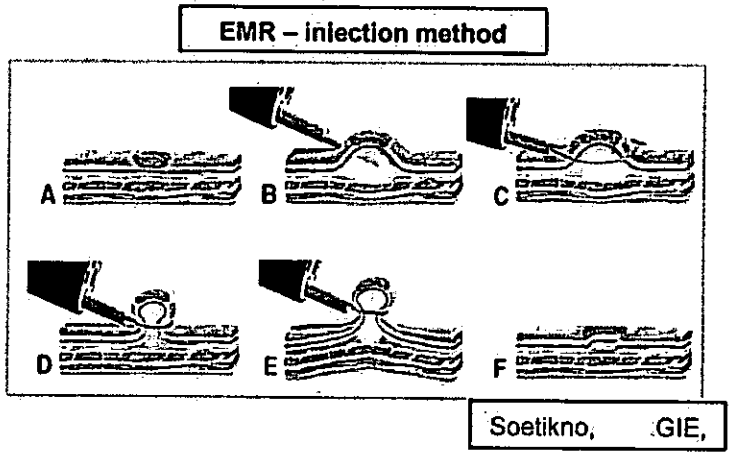

Figure 1

(A) The lesion is examined carefully and the border is defined.
(B) The submucosa is injected with saline solution with a sclerotherapy needle.
(C) The snare loop is placed at the base of the lesion.
(D) The snare is closed.
(E) Lesion is cut with RF energy.
(F) Specimen is removed. The site is examined for evidence of residual lesion.

2. ***Methods and Models of Evaluating New Endoscopic Technology Prior to Clinical Use:***

The following statement is provided by Dr. David Carr-Locke, Director, The Endoscopy Institute, Brigham and Women's Hospital, Harvard Medical School, Boston, MA.

If further explanation of this model and its applicability to clinically-approved methodology is required, Dr Carr-Locke is willing, as one of the authors of the Ex-Vivo and In-Vivo Performance Test Protocols (see attached), to provide additional information, expertise and discussion.

"When new endoscopic devices are developed to assist with the technique of EMR, initial testing is required to prove efficacy and safety in a model as close to the human situation as possible. It has become standard practice to use the porcine gastrointestinal tract for testing and as ex-vivo and intact in-vivo models since the anatomical layers of the gastrointestinal tract wall (mucosa, submucosal, muscularis propria) are very similar to that of the human[8].

For the development of EMR devices, it is well-established in the research and clinical fields within gastroenterology that the response of porcine gastrointestinal mucosa, submucosal and muscularis propria to fluid injection, manipulation and resection accurately reflect the behaviour of human tissue to these same procedures.

Ex-vivo testing and training can be used for initial evaluation of a principle such as submucosal fluid injection together with measurement of appropriate parameters to determine the optimal tissue effect.

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[5] Waye JD. *Endoscopic mucosal resection of colon polyps.* Gastrointest Endosc Clin North Am 2001;11:537– 48.

[6] Karita M, Tada M, Okita K, Kodama T. *Endoscopic therapy for early colon cancer: the strip biopsy resection technique.* Gastrointest Endosc 1991;37:128–32

[7] J. Waye et al. *Colonoscopy: Principles and Practice, Chapter 36: "Difficult Polypectomy"* from Wiley-Blackwell Publishing, Ltd, 2004; (eBook excerpt) http://www.gastrohep.com/ebooks/ebook.asp?book=1405120800&id=1

[8] Soo HE et al *"Effectiveness of Sodium Alginate as a Submucosal Injection Material for Endoscopic Mucosal Resection in Animals"* Gut and Liver, Vol.1, Number 1, June 2007, pp 27-32

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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While in-vivo testing and training are necessary to simulate the 'real' equivalent to the human condition since tissue blood flow, normal tissue 'tone' and motility are also present. After in-vivo testing, organs can be removed and evaluated for safety factors such as excessive injury or perforation. Such studies precede and help plan first human use trials.*

3. ***Proving Substantial Equivalence:***

Building off of Section #1 – which discussed the established clinical methods of practice, etc for the predicate device as background information – this section goes into more detail in describing the *critical components/ design inputs* from the established clinical practice for EMR technique, as used in clinical practice, are discussed in more detail below and provide reasoning:

- *to support the predicate device's methodology for generating a submucosal lift / elevation,*
- *to identify its disadvantages and drawbacks, and*
- *to highlight the need for an alternative technological methodology (i.e.: performance specifications that differ from the predicate) in order to meet the requirements of the predicate's intended use and thereby justify substantial equivalence.*

With that information, the proposed device can be presented within the 510(k) by including the key information requested by the FDA standard for substantial equivalence**, which includes[11]

✓ ***Intended Use:*** *– Equivalent to the injection needle –*

Induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

✓ ***Accepted Clinical Methods of Practice:*** *– Per the Intended Use (i) and Section 1 of this response –*

- "Saline Injection for Polypectomy (SIP)", "Submucosal Injection Technique"[9]
- "Saline Assisted Polypectomy", "Injection Assisted Endoscopic Mucosal Resection (EMR)"[10]

✓ ***Technological / Clinical Specifications:*** *– Technological features / methodology for Substantial Equivalence –*

- The proposed ERBELIFT Device's technological modalities *differ* from that of the predicate Injection Needle,
- But, both devices are *similar* since they share:
  - Equivalent Intended Use (i).
  - Comparable Performance Outputs for safety and effectiveness testing – based on published accepted clinical methods of practice (ii) for the predicate device.

***Note: Substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards, and other characteristics, as applicable.*[11]

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[9] J. Waye et al. *Colonoscopy: Principles and Practice, Chapter 36: "Difficult Polypectomy"* from Wiley-Blackwell Publishing, Ltd, 2004; (eBook excerpt) http://www.gastrohep.com/ebooks/ebook.asp?book=1405120800&id=1

[10] Sergey V. Kantsevoy, et al. Prepared by: ASGE TECHNOLOGY COMMITTEE. *Endoscopic mucosal resection and endoscopic submucosal dissection. Gastrointestinal Endoscopy.* July 2008 (Vol. 68, Issue 1, Pages 11-18)

[11] FDA Device Regulation and Guidance: *"Premarket Notification (510k) - What is Substantial Equivalence"*, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#se*

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The following sections provide the detail and relationship of the ERBELIFT Performance Test Aims, Goals, and Requirements that are in question, to the clinical practice and methodology (Section 1).

- Section (3.1) identifies the 'critical components / design inputs', for successful EMR Procedures and Technique - supported by the referenced peer review publications (footnotes)
- Section 3.2 is the ERBELIFT Performance Test Plan – based on the indentified critical clinical method requirements (section 1) and critical component performance requirements (Section 3.1)

3.1. *Critical Components for EMR Methodology - Identified as Performance Test Requirements:*

A. Injection Fluid

Technological Modality – Predicate

- The fluid, injected through a long flexible endoscopic needle, may be saline with or without methylene blue to enhance visualization. Further studies need to be performed to assess the practicality of various other injection solutions.[9]

Technological Modality – Proposed

- The ERBELIFT uses saline only, as stated in the intended use, which is equivalent to that of the predicate injection needle.

B. Injection Site

Technological Modality – Predicate

- The injection needle may be placed into the submucosa just at the edge of a polyp, or if the polyp is large and flat, multiple injections may be given around the polyp or directly into the middle of the polyp.
  - *Incorrect Placement:*[9]
    - If a bleb does not form at the injection site when 1 mL of fluid has been given, the needle should be withdrawn since the tip may have penetrated the wall and pierced the serosal surface.
    - If the needle placement is too superficial, the fluid will leak out from the bevelled edge and spill into the lumen. This spilling is especially noticeable when a colored fluid is used, such as methylene blue.
    - Multiple repeated needle placements and attempts at injection may be required to locate the correct plane for polyp elevation.
  - *Correct Placement :*[9]
    - When the needle is in the desired submucosal plane, continuous injection of saline will result in submucosal infiltration of fluid.
    - A large localized fluid collection is the desired endpoint, with marked elevation of the polyp.
    - When the tissues expand in response to fluid injection, the fluid is being deposited in the areolar tissue of the submucosal layer since neither the mucosa, muscularis propria, or the serosa will accept injected substance.

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Technological Modality – Proposed

The ERBELIFT system provides an alternative technological means for submucosal fluid injection without using a needle to breech the mucosa. ERBELIFT probe is placed directly against the mucosa at the desired location without mechanical force since, in this needle-less system, only the peak flow rate water stream breaches the mucosa and not the flexible probe itself.

The Hand Pump is used to easily generate the necessary input linear driving force to push the plunger of the fluid filled syringe, which in turn forces the fluid out of a micron sized distal orifice at the output flow rate specification required for a needle-less water stream to breech the mucosa and to fill the submucosa with saline.

Under direct endoscopic visualization, hand pump activation rates may slowly be increased, until the necessary flow rate is achieved to generate a submucosal lift in varying types of tissue types (increased wall thickness, mechanical tissue resistance, etc). While similar pressures and flow rates can be achieved with the proposed and predicate devices, the variability in pressure that can be generated by pushing on the syringe plunger depends upon the individual operator. When the trigger of the Hand Pump is squeezed faster, the flow rates and pressures increase just like when the plunger is manually pushed harder with predicate devices. Except for the differences between individual operators (cannot be controlled with the predicate device), the mechanical drive, orifice size, syringe, and probe limit the maximum flow rate. Both the predicate and subject devices operate with very similar variability. The key here is that with both the proposed and predicate devices, lifting is performed under direct visualization.

The potential advantages of the ERBELIFT system are the absence of any risk of needle-induced damage to the operative channel of the endoscope as well as the reduced risk of bowel wall perforation. Unlike the predicate needle device which uses a solid needle to "blindly" find the submucosal tissue plane, a minimum pressure or fluid flow rate is utilized to penetrate the mucosa with the subject device. As soon the fluid stream comes in contact with resistance (i.e.-tissue, fluid collection in the submucosa), the fluid continues to follow the path of least resistance and collect in the submucosa – because loose areolar tissue, in which fluid may collect, only exists in the submucosa. The muscularis propria layer creates a physical barrier against which the fluid expands laterally, leading to immediate elevation of the mucosal lesion. Very high pressures are needed to damage the muscularis layer in an animal model, but this is controlled by direct visualization by the operator.

C. Injection Volume

Technological Modality – Predicate

- When attempting SIP/EMR, there is no a specific volume of fluid which is used, but rather, the desired end point is a submucosal swelling beneath the polyp and adjacent portions of the mucosa controlled by visual assessment of the endoscopist.
- Elevation of the polyp may take 3–4 mL of saline given in several places, although some authors use up to 30 mL of fluid.[12]

Technological Modality – Proposed

- The ERBELIFT system, like the predicate, will deliver as little or as much fluid into the submucosa as the physician wishes. The desired endpoint for mucosal elevation prior to EMR is controlled entirely by direct visualization of the physician. (See section B – Correct Placement)

D. The Non-lifting Sign

Technological Modality – Predicate

- If a polyp fails to elevate (the 'non-lifting sign') it may be an indication of infiltration by cancer into the submucosa, with fixation by tumor limiting the expansion of the submucosal layer.[9]

[12] Waye JD. *Endoscopic mucosal resection of colon polyps.* Gastrointest Endosc Clin North Am 2001;11:537– 48.

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- Although too deep or too superficial needle placement may be the cause for failure to raise a bleb under a polyp, a submucosal bulging or bleb on one side of a polyp in response to injection without any visible elevation of the tumor itself is a clue that there is fixation to the submucosa.

Technological Modality – Proposed

- The ERBELIFT system will likely perform similarly to the predicate since fluid will expand in the submucosa by spreading through the loose areolar connective tissue and not through the deep tethering caused by malignant infiltration. Control of the elevation is entirely by visual inspection.

3.2. *Performance Testing Criteria: Summary of Test Plan*

Based on the discussion in sections 1 – 3.1, to support the the rationale behind the specific aims, goals, methodology and conclusions used for the ERBELIFT Performance Testing (ex- vivo and in-vivo) to support substantial equivalence, the following is an outline of the actual Performance Testing requirements for this submission: The full test plan is a seprate document: "ERBELIFT Performance Test Plan".

Purpose

i. To evaluate the technical feasibility output performance of the ERBELIFT Prototype System Rev A which consists of the following:

- *Flexible Probe Prototype (design option A: Tapered Distal Tip // .005" inner diameter tip opening)*
- *Prototype Hand Pump (force amplifier)*
- *Standard Control Syringe (10 cc)*

ii. Assess the if we can prove the ERBELIFT system's performance and intended use to be Substantially Equivalent to the Injection Needle – comparing output performance results against the:

- *Carr-Locke Injection Needle or equivalent*
- *Hand Force (under direct visualization per the IFU)*
- *Standard Control Syringe (10 cc)*

Goals / Aims of the Studies

The investigators used prototype versions of the ERBELIFT system for effectiveness of creating a submucosal elevation / lift, under direct endoscopic visualization, with performance comparable to an injection needle in the ex-vivo porcine stomach and the in-vivo porcine colon in order to:

- Evaluate the technical feasibility of needle-less method to create a submucosal elevation / lift using the ERBELIFT Hand Pump and Needle-less Flexible Probe -- ***Ex-Vivo Trial #1***
- Evaluate the most optimal technique to create a submucosal elevation / lift using the needle-less ERBELIFT system and compare results to the standard injection needle method -- ***Ex-Vivo Trial #2***
- Compare the efficacy and efficiency of performance outputs, specifically of creating Submucosal Elevation / Lift, of the ERBELIFT needle-less system to the standard Injection Needle Method -- ***In-Vivo Trial***
- Make recommendations for improvement of the prototype ERBELIFT system device.

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Exhibit 2, ERBELIFT™ Performance Test Plan (Note: Results/Conclusions are Included)

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ERBE
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ERBELIFT™ Performance Test Plan

EX-VIVO PORCINE STOMACH MODEL
AND
IN-VIVO LIVE ANESTHETIZED PORCINE MODEL

WRITTEN BY: **Erica Matthes**
Technical Product Manager, ERBE USA

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ERBELIFT Performance Test Plan

EX-VIVO PORCINE STOMACH MODEL
AND
IN-VIVO LIVE ANESTHETIZED PORCINE MODEL

Background

Endoscopic mucosal resection (EMR) is acknowledged as a curative therapeutic modality in the treatment of early gastrointestinal cancers[1]. Submucosal injection with saline is used to prevent complications[2]. When solutions like normal saline are injected submucosally, the mucosa lifts isolating the lesion and protecting the muscularis propia from injury and perforation.

Endoscopic mucosal resection (EMR) is mainly accomplished by the "lift" and cut method[3,4]. The "lift" of the tissue is important to decrease complications such as perforation when cutting the mucosa. Loss of mucosal "lift" prior to submucosal dissection or EMR increases the risk of complications[5].

Reasons for "lift" loss include time spent locating the submucosal plane using an injection needle. There have been no commercially available alternative methods for achieving a needle-free tissue "lift." A novel hand-pump needle-less elevation system (ERBE-USA, Marietta, GA), has been developed.

Purpose

- To evaluate the technical feasibility output performance of the ERBELIFT Prototype System Rev A which Consists of the following:
  - *Flexible Probe Prototype (design option A: Tapered Distal Tip // .005" inner diameter tip opening)*
  - *Prototype Hand Pump (force amplifier)*
  - *Standard Control Syringe (10 cc)*

- Assess the if we can prove the ERBELIFT system's performance and intended use to be Substantially Equivalent to the Injection Needle – comparing output performance results against the:
  - *Carr-Locke Injection Needle or equivalent*
  - *Hand Force (under direct visualization per the IFU)*
  - *Standard Control Syringe (10 cc)*

Goals / Aims

The investigators used prototype versions of the ERBELIFT system for the following study goals / aims:

1) *Effectiveness of creating a submucosal elevation / lift under direct endoscopic visualization,*
2) *Performance Outputs comparable to an injection needle in the ex-vivo porcine stomach and the in-vivo porcine colon in order to:*

   a) Evaluate the technical feasibility of needle-less method to create a submucosal elevation / lift using the ERBELIFT Hand Pump and Needle-less Flexible Probe -- ***Ex-Vivo Trial #1***

   b) Evaluate the most optimal technique to create a submucosal elevation / lift using the needle-less ERBELIFT system and compare results to the standard injection needle method -- ***Ex-Vivo Trial #2***

   c) Compare the efficacy and efficiency of performance outputs, specifically of creating Submucosal Elevation / Lift, of the ERBELIFT needle-less system to the standard Injection Needle Method -- ***In-Vivo Trial / IACUC Animal Study***

   d) Make recommendations for improvement of the prototype ERBELIFT system device

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ERBELIFT Performance Test Plan

EX-VIVO PORCINE STOMACH MODEL

AND

IN-VIVO LIVE ANESTHETIZED PORCINE MODEL

Methodology

a) Ex-Vivo Model

- A standard ex-vivo porcine stomach model was prepared from freshly harvested material and mounted on a purpose-designed plastic frame with the duodenum cross-clamped. The stomach was irrigated with normal saline as necessary to provide a clear mucosal field for the endoscopic experiments.

- *Due to different stomach wall thicknesses and the mechanical behavior of the gastric mucosa of the pig in different areas of the stomach, tests for upper, middle and lower thirds of the stomach were carried out and assessed.* The porcine stomach has the greatest similarity to human anatomy in its upper third[6].

b) In-Vivo Model

- Reference CBSET Animal Facility Protocol # WYO00001; IACUC Project Number: 100012

- Pigs (>25 kg Yorkshire pigs) were prepared in a standard fashion as per protocol and anesthetized to allow access to the upper and lower gastrointestinal tracts.

1. Ex-Vivo Trial #1 – Technical Feasibility

Reference Protocol 1 and Report – "Technical Feasibility Protocol for the evaluation of the ERBELift Prototype System Rev. A: Flexible Probe and Hand Pump (Force Amplifier)"

- Normal saline was used with the ERBELIFT system.

- The flexible probe was passed through a standard endoscope and gently placed directly against the mucosa at the desired location without force since, in this needle-less system, only the water stream breaches the mucosa and not the flexible probe itself (no mechanical injection).

- The Hand Pump is used to easily generate the necessary input linear driving force to push the plunger of the fluid filled syringe, which in turn forces the fluid out of a micron sized distal orifice at the output flow rate specification required for a needle-less water stream to breech the mucosa and to fill the submucosa with saline.

- The investigation began with the evaluation of the lowest input hand pump activation rate / input force possible to generate enough output fluid speed (volume over time) for a submucosal lift under direct visualization.

- These resultant input hand pump activation rates to output flow rate measurements were used as a baseline for specification development of the ERBELIFT Hand Pump and Probe functionality.

- An input 'pressure' measurement generated by the hand pump to the fluid filled syringe could only be measured as an approximation, and recorded only as an investigational specification value during this Ex-Vivo Trial.

  - This is because the hand pump applies an *input linear force* to the plunger of the fluid filled syringe *over a set distance* per pull of the trigger, pushing the fluid out of the syringe at a certain speed – which equates to a output volume flow rate (volume/ time).

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ERBELIFT Performance Test Plan

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- Under direct endoscopic visualization, hand pump activation rates may slowly be increased, until the necessary flow rate is achieved to generate a submucosal lift in varying types of tissue types (increased wall thickness, mechanical tissue resistance, etc). As soon the fluid stream comes in contact with resistance (i.e.-tissue, fluid collection in the submucosa), the fluid continues to follow the path of least resistance and collect in the submucosa -- because loose areolar tissue, in which fluid may collect, only exists in the submucosa

- Pressure is a Force per unit Area measurement, and approximation of minimum input pressure values could only be measured using a pressure gauge attached to the syringe/ flexible probe connection point and was loosely correlated to the output flow rate and input hand force / activation rate generated from the Hand Pump. Pressure measurements are dependent on the surface area, fluid viscosity, backpressure, etc, and are difficult to measure at an input without specific locked design specifications.

- Except for the differences between individual operators (cannot be controlled with the predicate device), the mechanical drive, orifice size, syringe, and probe limit the maximum flow rate. Both the predicate and subject devices operate with very similar variability. The key here is that with both the proposed and predicate devices, lifting is performed under direct visualization.

- An injection needle utilizes variable hand force applied to the syringe to generate an output flow rate and also variable push force to penetrate the mucosa and position the needle in the correct submucosal plane. No hand force was recorded on the syringe and injection needle, since the performance output was designated by direct visualization.

- The hand force / activation rate applied to the hand pump, whether slow, medium or fast was correlated to flow rate output, based on the volume of fluid and time taken to create a 'visible' submucosal lift.

Goals –

a. In order to identify the *feasibility specifications for needle-less elevation / lift*, a slow pull rate was applied to the hand pump, thereby pushing the fluid filled syringe at a slow consistent flow rate – increasing the trigger speed until the submucosal cushion was visualized by the operator – thus providing the minimal flow rate specification for the needle-less water stream to breech the mucosa and to fill the submucosa with saline.

b. In order to determine *optimal hand pump activation, related to submucosal cushion* as assessed by direct visualization, different levels of hand force applied to the Hand Pump, starting from very slow trigger pulls up to fast trigger pulls were used to determine the volume / time or flow rate necessary to create the desired submucosal cushion in varying types of tissue (wall thickness, mechanical tissue resistance, etc.).

Conclusions –

- The investigators concluded that the ERBELIFT system met the intended use specifications,
- Mucosal elevation was highly reproducible based on desired tissue effect,
- Initial experience suggested this technology could produce tissue effects comparable with needle injection for EMR.

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ERBELIFT Performance Test Plan

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2. Ex-Vivo Trial #2 – Optimal Technique

Reference Protocol 1 and Report -- "Mucosal Tissue Elevation Utilizing a Novel Handheld Needle-less System for Tissue Elevation"

- Normal saline was used with the ERBELIFT system.
- The flexible probe was passed through a standard endoscope and gently placed directly against the mucosa at the desired location without force since, in this needle-less system, only the water stream breaches the mucosa and not the flexible probe itself (no mechanical injection).
- The aim was to determine if the ERBELIFT system improved overall procedure time (efficiency), quality of the submucosal elevation (lift), method of generating force required for fluid delivery to the submucosa, and safety when compared to the traditional needle injection system.
- Three levels of physician expertise were also tested. Each of the three arms consisted of different individuals who performed the injections with both the hand pump (force amplified) needle-less elevation system (ERBE USA, Inc.), and traditional injection needle system. The first arm was conducted by a master clinician (attending gastroenterologist), the second arm by a gastroenterology fellow, and the third arm by a novice (individual who has never performed endoscopy). These individuals were selected from the academic institution where the research will occur.
- Stomachs from five (> 25 Kg, Yorkshire pigs) were used. Each of the three arms consisted of a different individual who performed the injections with both ERBELIFT (force amplified) needle-less elevation system and traditional injection needle system.
- The following parameters were evaluated: Height of Elevations, Time to inject 10cc saline with the endoscope 1 cm away from the target, Pressure in the syringe system, Flow Rate, Safety on tissue, Ease of use, Accuracy and Diameter of the blebs.
- Five endoscopists performed 10 tissue elevations each – 5 with the traditional needle, and 5 with the ERBELIFT system.
- Mucosal lift was accomplished in 100% of the needle-less group and 92% in the needle group, independent of the endoscopist skill level.
- There were no perforations.
- The needle-less system was rated simple to use in 92% while the needle system was 64% ($p=0.02$).
- Accuracy was <3mm in 100% with the needle-less system and <3mm in 76% with the needle system ($p=0.01$).
- There was no significant difference between the needle-less and needle group for height of elevation or flow rate.
- Total procedure time was less in the needle-less group ($p<0.01$) and yielded greater maximum lift diameters ($p=0.03$).
- The investigators concluded that the ERBELFT system improved procedure time, was easy to use, yielded greater lift diameters and caused no perforations.
- In-vivo studies were needed to validate these findings in living tissue.

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ERBELIFT Performance Test Plan

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3. In-Vivo Trial –

Reference CBSET Animal Facility Protocol # WYO00001; IACUC Project Number: 100012

- On the basis of the ERBELIFT ex-vivo technical feasibility and comparative studies to determine minimum flow rate in attaining a needle-less submucosal breech and optimal ERBELIFT system performance / functional techniques to create a submucosal lift / elevation, submucosal cushions were created in-vivo in different areas of the colon and their sizes were measured objectively.

- Experimental fluid cushions of saline were created as a control, to identify the constant – volume. This was identified by visualization of an ideal 'polyp'. Based on the pseudopolyp created with between 1 – 2 ml of saline, the volume of 1.5ml, which is equivalent to 2 full trigger pulls of the hand pump, was chosen as the constant.

- The duration time of saline submucosal injection to 1.5ml was recorded and the bleb size created was recorded with endoscopic images for comparison of bleb size to flow rate – to support substantial equivalence.

- 1 endoscopist (master clinicians), 1 trainee, and 1 novice were selected to perform 20 tissue elevations, using 1.5mL of blue-colored normal saline, 10 with the novel hand-pump needle-less elevation system and 10 with a traditional needle injection system in a live porcine model a : >25 kg Yorkshire pig.

- Perforation rate was also evaluated as a worse case test – by applying intentional maximum force on the hand pump in the thin walled colon. This was defined as the maximum pull / activation force applied to the trigger of the hand pump by the user, and deliberately ignoring the visual tissue effect – essentially simulating negligent use of the product.

- Flow rate peaks were recorded, and potential damage to the muscularis was examined by excising the organ and completing a leak test.

- There was no statistical difference between the needle-less and needle group or flow rate (0.39 ±0.05 mL/s vs. 0.36 ±0.07 mL/s, respectively, $p = 0.36$).

- There were no perforations at maximum force.

- The investigators concluded that the ERBELIFT system performed as well as the needle system and that the results of ex-vivo results could be validated in living tissue.

Please reference Test Protocols and Reports for Additional Information and Detailed Results.

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ERBELIFT Performance Test Plan

EX-VIVO PORCINE STOMACH MODEL

AND

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3 Arebi N, Swain D, Suzuki N, et al. Endoscopic mucosal resection of 161 cases of large sessile or flat colorectal polyps. Scandinavian Journal of Gastroenterology 2007;42:859-866.

4 Bories E, Pesenti C, Monges G, et al. Endoscopic mucosal resection for advanced sessile adenoma and early-stage colorectal carcinoma. Endoscopy 2006;38:231-235.

5 Hurlstone DP, Fu KI, Brown SR, et al. EMR using dextrose solution versus sodium hyaluronate for colorectal Paris type I and 0-II lesions: a randomized endoscopist-blinded study. Endoscopy 2008;40:110-114.

6 Fujishiro et al. *Comparison of various submucosal injection solutions for maintaining submucosal elevation during endoscopic submucosal resection.* Endoscopy 2004;36:579-583.

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Exhibit 3, Testing Report (Results) of Feasibility Protocol, Ex-Vivo Trial 1

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TITLE: **RESULTS: Technical Feasibility Protocol for the evaluation of the ERBELIFT Prototype System Rev. A: Flexible Probe and Hand Pump (Force Amplifier).**

STUDY NO: *Protocol 1 (Feasibility – for Design Select)*

DATE: September 30, 2008

WRITTEN BY: **Erica Matthes**
Technical Product Manager, ERBE USA

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Technical Feasibility Evaluation of the ERBELIFT Prototype System Rev A: Flexible Probe and Hand Pump (Force Amplifier).

I. Purpose:

i. To evaluate the technical feasibility output performance of the ERBELIFT Prototype System Rev A which consists of the following:

- *Flexible Probe Prototype (design option A: Tapered Distal Tip // .005" Inner diameter tip opening)*
- *Prototype Hand Pump (force amplifier)*
- *Standard Control Syringe (10 cc)*

ii. Assess the if we can prove the ERBELIFT system's performance and intended use to be Substantially Equivalent to the Injection Needle – comparing output performance results against the:

- *Carr-Locke Injection Needle or equivalent*
- *Hand Force (under direct visualization per the IFU)*
- *Standard Control Syringe (10 cc)*

II. Goals / Aim

Using the following criteria, the goal of this technical feasibility study will determine if the ERBELIFT Prototype System Rev A meets or exceeds its intended use specifications, and also determine if the initial results support substantial equivalence to the injection needle.

i. Determine the minimum flow rate (and corresponding input pressure) required for a needle-less breach of the mucosa for the ERBELIFT Prototype Rev A system.

ii. Evaluate substantial equivalence based on the following performance testing of the ERBELIFT System to the Injection Needle (see section 3.0 of this protocol), specifically looking at:

- Flow Rate Output to Approximate Input Pressure Performance.
- Desired Tissue Effect under Direct Visualization

If these goals are met, we can deem the ERBELIFT Prototype System Rev A as the 'Design Select' and move on to the next project phase: Design Verification and Validation.

III. Materials:

- ERBELIFT Flexible Probe – Prototype A (tapered tip)
- ERBELIFT Hand Pump – (18:1 Power Ratio – Easy Push) Prototype
- Carr-Locke Injection Needle or equivalent
- Standard Control Syringe – Deroyal 10cc
- Pressure Gauge – US Gauges (Manufactured for Merit Medical) – 0 PSI- 480 PSI +/- 5 PSI *[for investigational measurements only, to be attached to a standard control syringe for both the ERBELIFT and Injection Needle test devices, for measuring approximate input pressures only]*
- Ex-Vivo Tissue Sample: Large Intestine (swine)
- Normal Saline 0.9%
- Methylene Blue (or equivalent)
- Digital Camera
- Standard ruler
- Stopwatch

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IV. Methods:

The technical feasibility evaluations will consist of the following performance tests. Each specific feasibility test protocol will list the product(s) to be tested, sample size, performance requirements, and results.

i. *ERBELIFT Minimum Flow Rate Evaluation – to attain a Needle-less Submucosal Breech*

- Operate the ERBELIFT Prototype Rev A System per it's intended use under direct visualization
- Measure the flow rate (volume / time)
- Using the attached pressure gage, assess the associated approximate input pump pressures.

ii. *Input (Approximate) Pressure to Output Flow Rate Performance – to attain a submucosal lift*

- The ERBELIFT Prototype A System and the comparison products will be subjected to equivalent pressure / force variables applied to the syringe to attain a submucosal lift (e.g. pre EMR procedures) under direct visualization (per the IFU)
- Each test sample will be subjected to an equivalent range of a slow, medium and fast method of driving the piston of the fluid filled syringe forward (either hand activation – needle or hand pump activation – ERBELIFT) to attain a submucosal lift under direct visualization.
- Measure the flow rate (volume / time) for each test group.
- Using the attached pressure gage, assess the associated approximate input pump pressure.
- Each test sample should be able to withstand the specified outputs without failure (e.g.: leaking of saline at points of the device other than the distal tip, other failure modes, etc)

Table #1

Test Samples *ml/min = milliliters/minute		Slow Injection (100-180 PSI)	Medium Injection (180-260 PSI)	Fast Injection (260-340 PSI)
ERBELIFT Prototype A System	Sample #1	12.6 ml/min	27.6 ml/min	50.4 ml/min
	Sample #2	16.8 ml/min	27 ml/min	42.6 ml/min
	Sample #3	16.2 ml/min	31.2 ml/min	41.4 ml/min
	Average	15.2 ml/min	28.6 ml/min	44.8 ml/min
	Std dev	2.3 ml/min	2.3 ml/min	4.9 ml/min
	Peak PSI	180 PSI	260 PSI	340 PSI
Carr-Locke Needle & Syringe (hand force)	Sample #1	14.4 ml/min	28.2 ml/min	52.8 ml/min
	Sample #2	16.8 ml/min	34.8 ml/min	45.6 ml/min
	Sample #3	15.6 ml/min	31.8 ml/min	42.6 ml/min
	Average	15.6 ml/min	31.6 ml/min	47 ml/min
	Std dev	1.2 ml/min	3.3 ml/min	5.2 ml/min
	Peak PSI	180 PSI	260 PSI	340 PSI

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iii. *Input (Approximate) Pressure to Output Flow Rate Performance – Result Comparison*

- The ERBELIFT Prototype A System and the Carr-Locke Needle test subjected to equivalent pressure / force variables applied to the syringe to attain a submucosal lift (e.g. pre EMR procedures) under direct visualization (per the IFU). In all cases, both sets of test samples performed within the guidelines of the study design and did not exceed the parameters associated with the intended use.
- The flow rate was measured using the following formula, volume (10 ml) / time – The primary flow rate variance is associated with the differences between individual operators, specifically the manual pressure or force applied to the syringe by the different test subjects.
- Each test sample was able to withstand the specified outputs without failure (e.g.: leaking of saline at points of the device other than the distal tip, other failure modes, etc).
- When comparing both the needle-less and needle groups, there was no significant statistical difference when slow, medium, or fast pulls were used.
- In all cases, submuscoal elevations were achieved.
- The test results were recorded in the table above (Table 1) and have accompanying digital images of the outputs below.

ERBELIFT Sample #1 **ERBELIFT Sample #2** **ERBELIFT Sample #3**

Carr-Locke Sample #1 **Carr-Locke Sample #2** **Carr-Locke Sample #3**

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iv. ***Tissue Effect: Bleb Size to Volume Comparison:***

The ERBELIFT Prototype A System and the comparison products will be subjected to equivalent pressure / force variables applied to the syringe to attain a submucosal lift (e.g. pre EMR procedures) under direct visualization (per the IFU)

Each test sample will be evaluated in the following manner with the following expectations:

- Create a baseline bleb (submucosal elevation - approximately 2" +/- 1" in diameter) with both the ERBELIFT Prototype A System and the Carr-Locke Needle at the specified pressures in ex-vivo Large Intestine tissue.
- Using a standard ruler, record the diameter and the height of the baseline blebs created with both systems.
- Record the Volume used to create the initial blebs.
- Use a stopwatch and set to 2 minutes post initial bleb formation.
- After 2 minutes, using a standard ruler, record the diameter and height of the blebs.
- Investigate different techniques for using the ERBELIFT hand pump prototype
- The test results are to be recorded in Table #3 and also include digital images of the ERBELIFT System A outputs.

Table #3

Test Samples		Initial Bleb Diameter & Height (mm)		Initial Bleb Volume (ml) of saline		Bleb – post 2 min. Diameter & Height (mm)	
ERBELIFT Prototype A System	Sample #1	S: 30 x 10	M: 30 x 11	S: 10 ml	M: 10 ml	S: 30 x 9	M: 30 x 9
		F: 30 x 11		F: 10 ml		F: 30 x 10	
	Sample #2	S: 30 x 10	M: 30 x 10	S: 10 ml	M: 10 ml	S: 30 x 9	M: 30 x 9
		F: 35 x 10		F: 10 ml		F: 35 x 10	
	Sample #3	S: 25 x 15	M: 30 x 13	S: 10 ml	M: 10 ml	S: 25 x 13	M: 30 x 11
		F: 35 x 9		F: 10 ml		F: 35 x 9	:
Carr-Locke Needle & Syringe (hand force)	Sample #1	S: 28 x 14	M: 33 x 9	S: 10 ml	M: 10 ml	S: 28 x 13	M: 33 x 8
		F: 30 x 10		F: 10 ml		F: 30 x 10	
	Sample #2	S: 30 x 11	M: 31 x 13	S: 10 ml	M: 10 ml	S: 30 x 10	M: 31 x 11
		F: 29 x 14		F: 10 ml		F: 29 x 13	
	Sample #3	S: 35 x 9	M 32 x 11:	S: 10 ml	M: 10 ml	S: 35 x 8	M: 35 x 10
		F:27 x 13		F: 10 ml		F: 27 x 12	

*** S= Slow (100-180 PSI)** **M= Medium (180-260 PSI)** **F= Fast (260-340 PSI)**
(reference Table 1)

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Technical Feasibility Evaluation of the ERBELIFT Prototype System Rev A: Flexible Probe and Hand Pump (Force Amplifier).

Pull	Initial	Post 2 minutes
Slow #1		
Slow #2		
Slow #3		

Pull	Initial	Post 2 minutes
Med #1		
Med #2		
Med #3		

Pull	Initial	Post 2 minutes
Fast #1		
Fast #3		

Pull	Initial	Post 2 minutes
Fast #2		

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V. Results and Goals:

The results of this technical feasibility protocol have determined that the ERBELIFT Prototype System A:

- *Meets the intended use* specification for submucosal elevation with an injection needle
- Meets the following parameters when compared to the control test device (Carr-Locke Needle):
  - Input to output performance results (including technique and ease of use) are measurable and consistent.
  - Tissue effect is highly reproducible and (bleb diameter and height over time) under direct visualization is indistinguishable from the control device (Carr-Locke Needle) at the input pressures equivalent to those used for GI submucosal elevation (see Section 4.0).
  - The initial ex-vivo results suggest that input pressures created by slow, medium, and fast depressions of the syringe plunger which are equivalent to those used for GI submucosal elevation are similar in both groups.
  - Minimal flow rates and low pressure needle-less injection (100-180 PSI) is technically feasible and has the potential to replace a more invasive technology

Based on the performance characteristics of both the industry standard needle injection system (Carr-Locke Needle) and the ERBELIFT Prototype System A, little difference is seen in the operation of either device from both a fluid delivery perspective and tissue effect. We can therefore deem the ERBELIFT Prototype System Rev A as the 'Design Select' and move on to the next phase: Verification and Validation.

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Exhibit 4,
Study Protocol and Report,
Ex-Vivo Trial 2

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Submucosal "Lift" utilizing a novel Hand-Held Needle-less System
Obstein KL, Maurice D, Matthes E, Thompson CC, Carr-Locke DL

Study Design/Protocol

I. Aim: To determine if a novel hand pump (force amplified) needle- less elevation system (ERBE USA, Inc.), when used in procedures where Selective Tissue Elevation (specifically submucosal "lifting") is desired, will improve overall procedure time (efficiency), quality of the submucosal elevation (lift), method of generating force required for fluid delivery to the submucosa, and safety when compared to the traditional needle injection system.

II. Hypothesis: The novel needle-less elevation system (ERBE USA, Inc.) will result in improved procedure time (efficiency) dedicated for submucosal elevation (lifting), an easier and less demanding method of generating force to drive the fluid delivery to the submucosa, as well as provide similar quality and safety of the submucosal elevation (lift) when compared to the traditional needle- injection system

III. Brief Background/Significance:
Endoscopic mucosal resection (EMR) is mainly accomplished by the "lift" and cut method [1,2]. The "lift" of the tissue is important to decrease complications such as perforation when cutting the mucosa. Loss of mucosal "lift" prior to submucosal dissection or endoscopic mucosal resection (EMR) increases the risk of complications [3].

There are many factors that influence loss of the lift including the type of needle used, the experience of the clinician, the appropriate deposition of the lifting solution in the correct tissue plane, the volume of lifting solution injected, and the duration of time required to obtain an adequate "lift." Until now, there has been no alternative method for achieving a tissue "lift" without using a needle based system. The novel hand pump (force amplified) needle-less elevation system (ERBE USA, Inc.), has been developed in order to facilitate the separation of tissue planes by utilizing a 120 micron stream of saline. This system may be useful in providing adequate "lift" for EMR and may improve overall outcomes as a result.

IV. Research Design and Methods:

a. Basic Study Design:
Observational three arm trial with each arm having the same case and control.

b. Assembly of subjects:
Porcine small intestine from five, greater than 25 Kg, Yorkshire pigs will be utilized to model the human colon. The porcine small intestine will be harvested from an animal facility and be delivered fresh to the wet-bench at the laboratory facility where the study will occur. Each of the three arms will

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consist of a different individual who will perform the injections with both the hand pump (force amplified) needle-less elevation system (ERBE USA, Inc.), and traditional injection needle system.

The first arm will be conducted by a master clinician (attending gastroenterologist), the second arm by a gastroenterology fellow, and the third arm by a novice (individual who has never performed endoscopy). These individuals will be selected from the academic institution where the research will occur.

c. Exposures:
Each arm of the study will consist of the associated individual performing submucosal "lifts" on 5 pieces of small intestine. Each individual piece will be its own case and control. Cases will be defined as utilizing the hand pump (force amplifier) needle-less elevation system (ERBE USA, Inc.) with 10 cc's of normal saline injected into the mucosa through a standard channel colonoscope (Olympus CF-Q160). Controls will be defined as utilizing the needle system by Olympus (Olympus disposal injector needle NM-200U-0423, 23G) with 10 cc's of normal saline injected into the mucosa through a standard channel colonoscope (Olympus CF-Q160). Each of the 5 pigs will have a piece of their small intestine utilized by each of the 3 individuals. In total each individual will complete 5 cases and 5 controls. The total number of cases will be 15 and the total number of controls will be 15. A small dot will be made utilizing a surgical marker that will serve as the intended site for the "lift."

V. Outcomes and their Measurement:

- *Height of Elevations:* Measured in millimeters immediately after a "lift" by a laser guidance system from the apex of the "lift" to the standard surface of the tissue at the bottom of the "lift."

- *Time:* Measured in seconds from the time the system is pushed out of the end of the endoscope to the time the 10 cc of normal saline is injected into the mucosa. The endoscope end will be 1 cm away from the target site before the system is pushed out the end.

- *Pressure:* Measured in bar, a pressure gage will be connected to the syringe system to measure the maximum pressure and minimum pressure once the lift has begun.

- *Flow Rate/Time:* Measured by the amount of volume in the normal saline syringe (10 cc) divided by the time in seconds to fully expel the volume in the syringe.

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- *Safety:* Measured by examining the tissue after injection to determine if any tears or perforations exist. This will be accomplished by tying one end of the tissue with suture, insufflating the tissue with air until inflated, submerging the tissue underwater, and observing for leakage of air/air bubbles.

- *Ease of use:* Each individual will assess this qualitatively for each of the cases and controls.

- *Accuracy:* Measured in millimeters from the target dot to the actual site of the apex of the "lift."

- *Diameter:* Measured in millimeters on two different axis positions.

VI. Analysis Plan:

Comparison of the cases, controls as a group of 30 (15 cases and 15 controls) and comparison of cases and controls by individual as groups of 10 (5 cases and 5 controls).

References:

1. Arebi N, Swain D, Suzuki N, et al. Endoscopic mucosal resection of 161 cases of large sessile or flat colorectal polyps. Scandinavian Journal of Gastroenterology 2007;42:859-866.

2. Bories E, Pesenti C, Monges G, et al. Endoscopic mucosal resection for advanced sessile adenoma and early-stage colorectal carcinoma. Endoscopy 2006;38:231-235.

3. Hurlstone DP, Fu KI, Brown SR, et al. EMR using dextrose solution versus sodium hyaluronate for colorectal Paris type I and 0-II lesions: a randomized. endoscopist-blinded study. Endoscopy 2008;40:110-114.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2011-1895; Released by CDRH on 09-20-2012.

Mucosal Tissue Elevation Utilizing a Novel Hand-Held Needle-less System

Background

Endoscopic mucosal resection (EMR) is primarily accomplished by performing tissue elevation or "lift," followed by excision of the lesion. The mucosal "lift" facilitates resection and dissection. Loss of mucosal "lift" increases risk of complications. Reasons for "lift" loss include time spent locating the submucosal plane using a needle. There have been no commercially available alternative methods for achieving a needle-free tissue "lift." A novel hand-pump needle-less elevation system (ERBE-USA, Marietta, GA), has been developed.

Aim

To determine whether a novel hand-pump needleless elevation system will affect procedure time and generate tissue elevation without complication when compared to a needle system.

Methods:

5 endoscopists (2 master clinicians, 2 trainees, and 1 novice) were selected to perform 10 tissue elevations, using 10 mL of blue-colored normal saline, 5 with the novel hand-pump needleless elevation system and 5 with a traditional needle injection system (Olympus, Tokyo, Japan) in a porcine stomach model. Each endoscopist was randomly assigned an individual, freshly harvested stomach from a >25 kg Yorkshire pig. Height of elevation (mm), procedure duration (s), perforation rate, ease of use (simple, fair, unacceptable), accuracy of elevation placement (within >3mm, 3mm, <3mm of intended target), diameter of bleb (2 axis in mm), and flow rate (mL/s) were recorded. Statistical analysis was performed to compare the needleless system to the needle system as an overall group.

Results:

Mucosal lift was accomplished in 100% of the needleless group vs. 92% in the needle group, independent of the endoscopist skill level. There were no perforations. The needleless system was rated simple to use in 92% (23/25) while the needle system was simple to use in 64% (16/25) of cases ($p=0.02$). Accuracy was <3mm in 100% with the needleless system and <3mm in 76% (19/25) with the needle system ($p=0.01$). There was no statistical difference between the needleless and needle group for height of elevation (15.27±4.99 v.15.84±5.5, respectively, $p=0.72$) or flow rate (0.61±0.09 v. 0.53±0.23, respectively, $p=0.1$). Total procedure time was less in the needleless group (19.36±3.35 v. 28.2±8.85, respectively, $p<0.01$) and yielded greater maximum lift diameters (40.18±10.26 v. 33.03±11.31, respectively, $p=0.03$).

Conclusions

The novel hand-pump needleless elevation system improved procedure time, was rated simple to use, and generated larger maximum diameter mucosal elevations without complication when compared to a traditional needle system. The needleless system will be useful in providing adequate mucosal elevation for EMR and may improve overall outcome.

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Exhibit 5,
Testing Protocol and Report,
In-Vivo Trial

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(b)(4) Contractor Test Study

Final Protocol

A Non-GLP Technical Feasibility Protocol for the evaluation of the ERBELIFT Prototype System Rev. A: Flexible Probe and Hand Pump (Force Amplifier) in a Porcine Model

(b)(4) Contractor Test Study

(b)(4) Contractor Test Study

Test Facility:

Study Director: (b)(4) Contractor Test Study

Sponsor: **ERBE USA ,**
2225 Northwest Parkway,
Mariettea, GA 30067

Date: **March 9, 2009**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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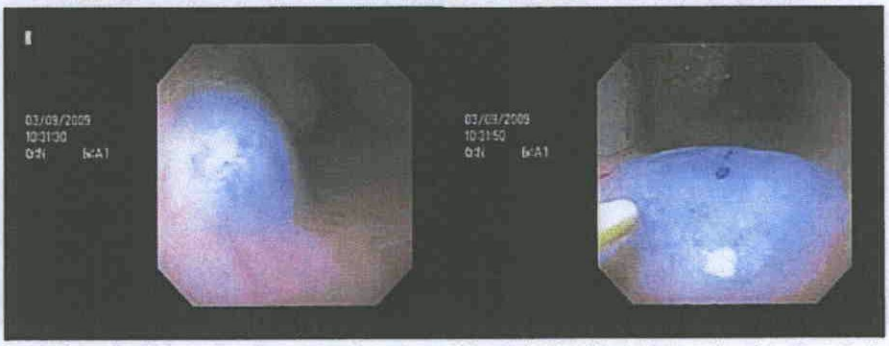
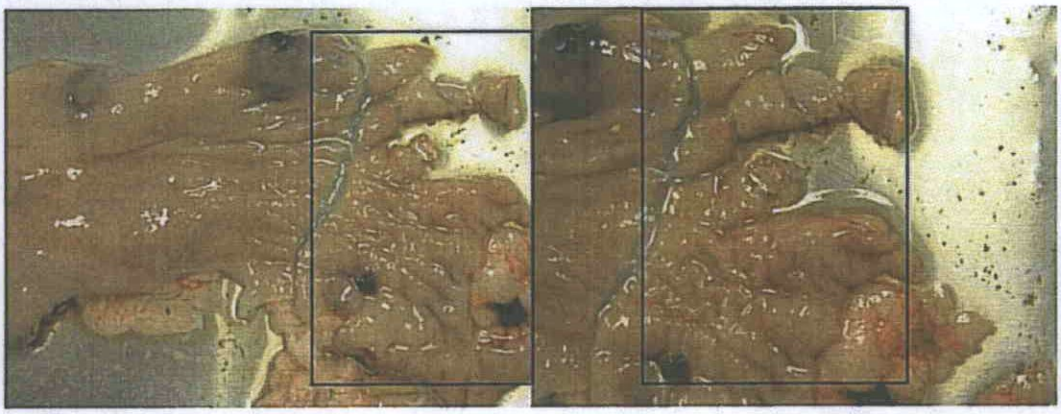
Attachment #1
ERBELIFT ANIMAL LAB 030909
CBSET, LEXINGTON, MA

SECTION I: - *the volume of 1.5ml, which is equivalent to 2 full trigger pulls of the hand pump, was chosen as the constant*





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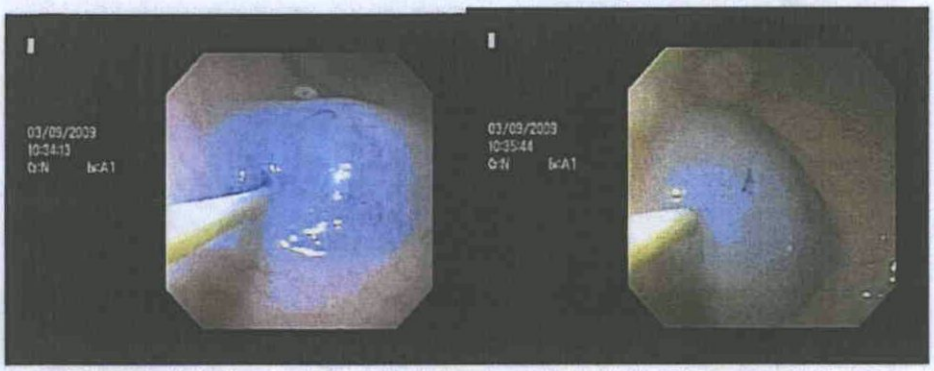
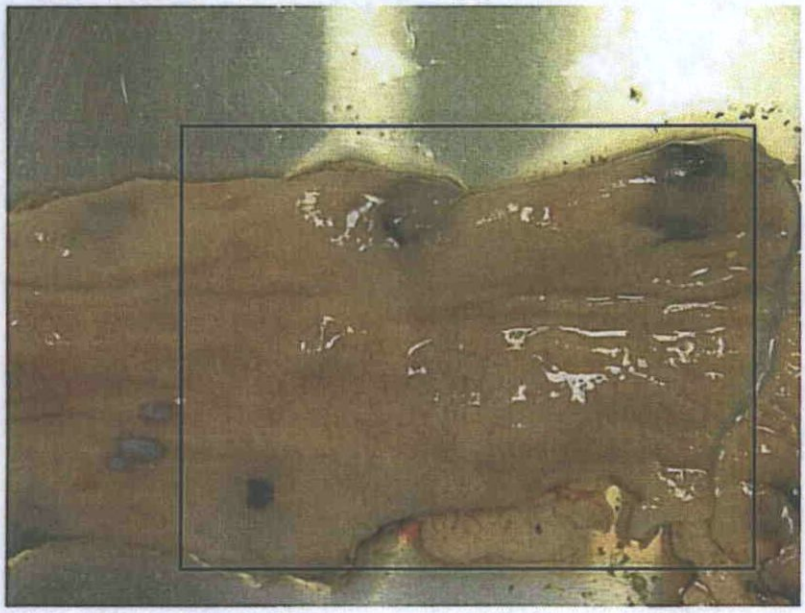
SECTION II: ERBELIFT A





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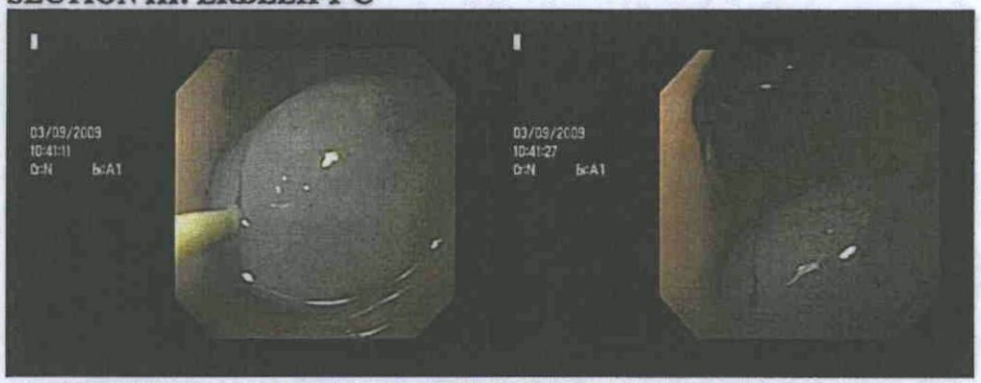
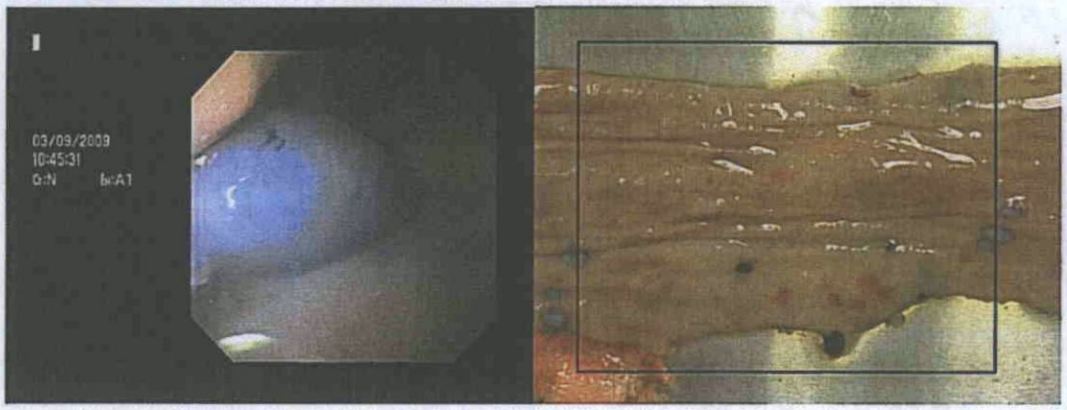
SECTION III: ERBELIFT C





116

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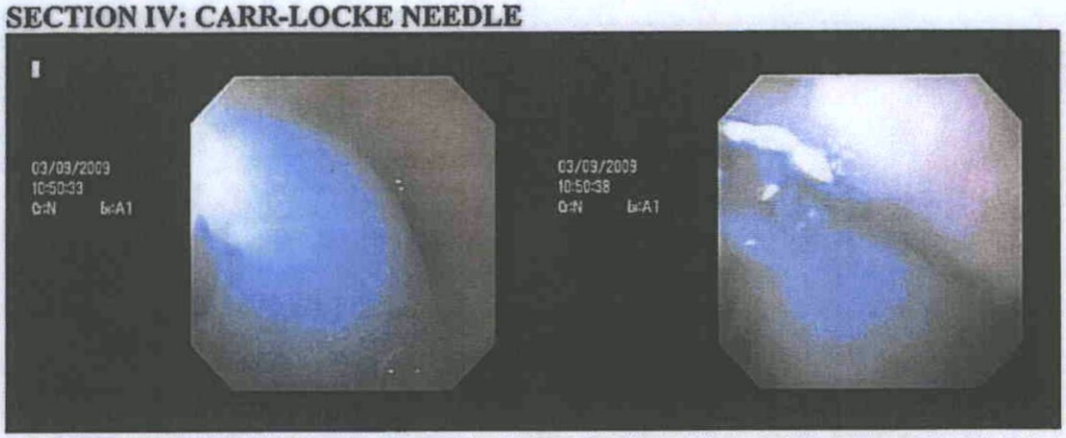
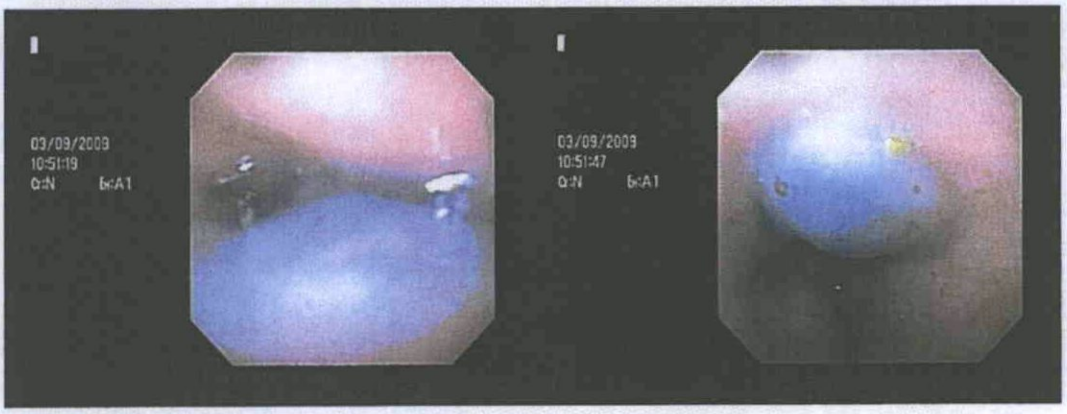
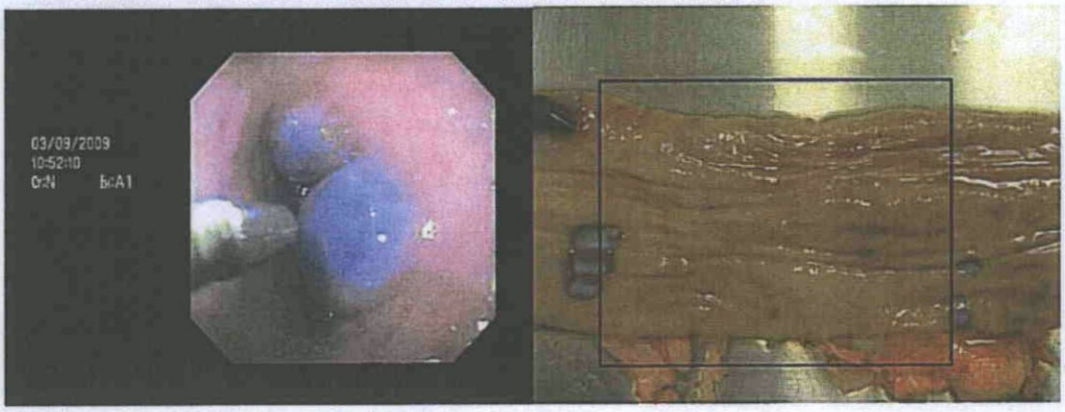
SECTION IV: CARR-LOCKE NEEDLE







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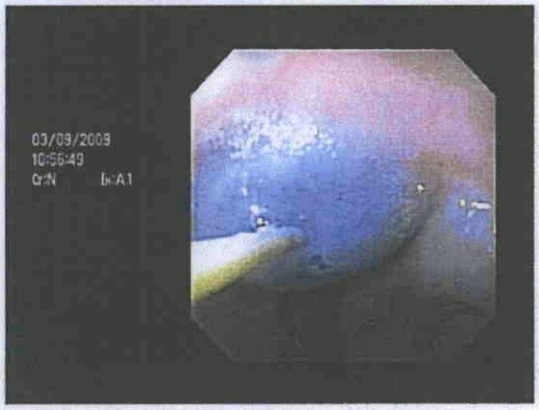
SECTION V: ERBELIFT A (NOVICE)



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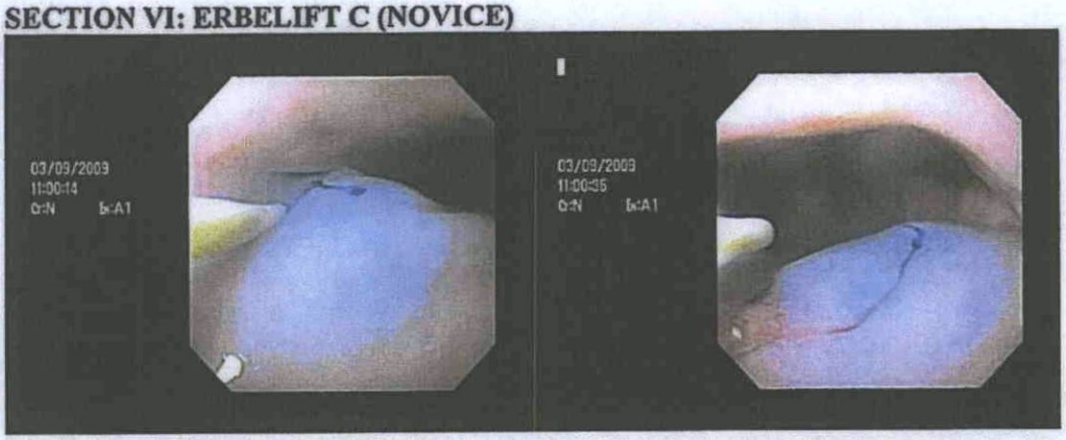
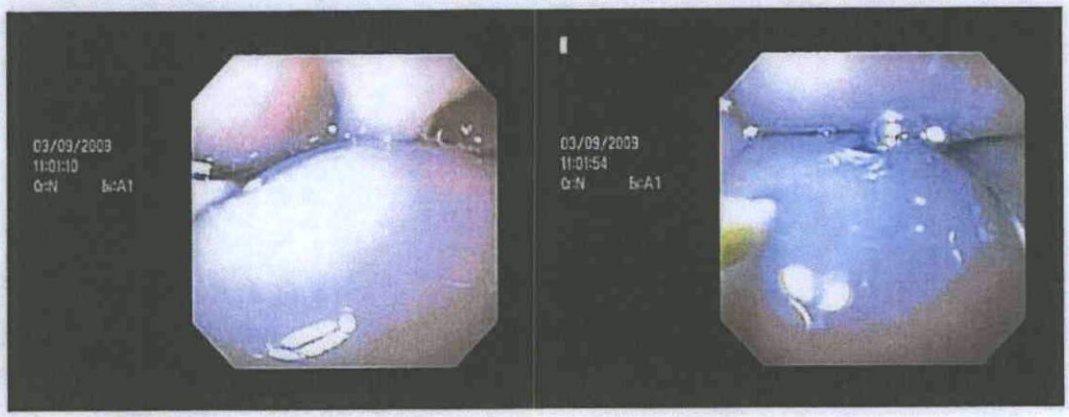
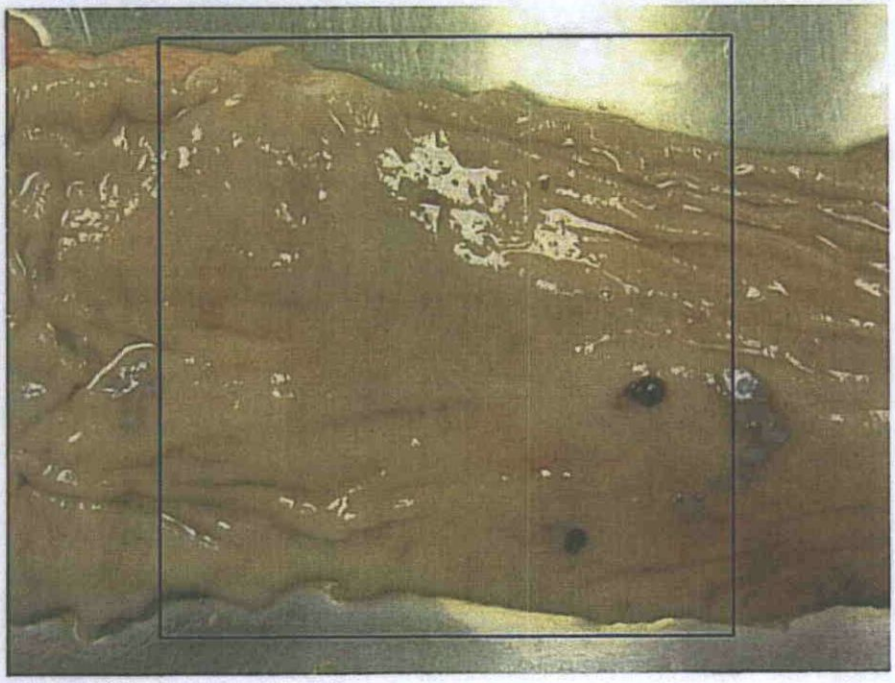
SECTION VI: ERBELIFT C (NOVICE)







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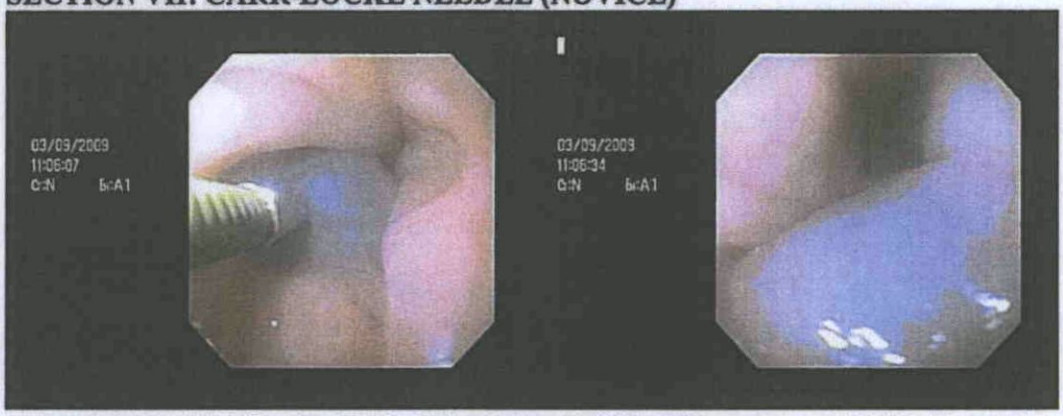
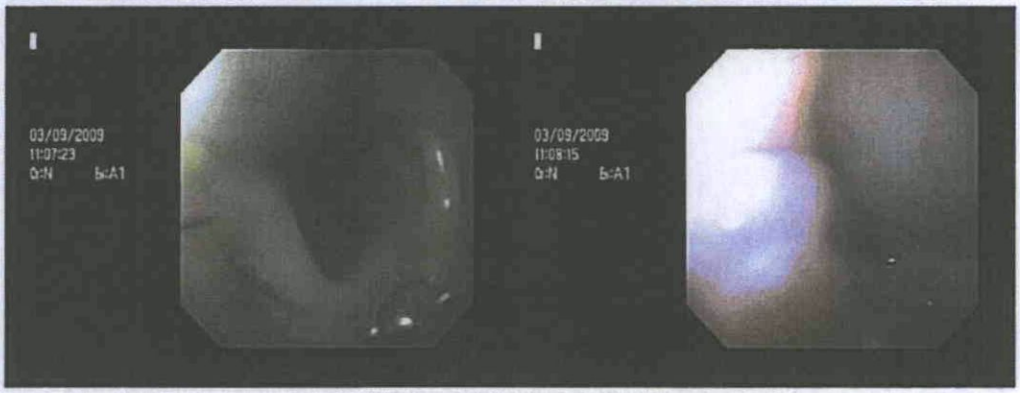
SECTION VII: CARR-LOCKE NEEDLE (NOVICE)





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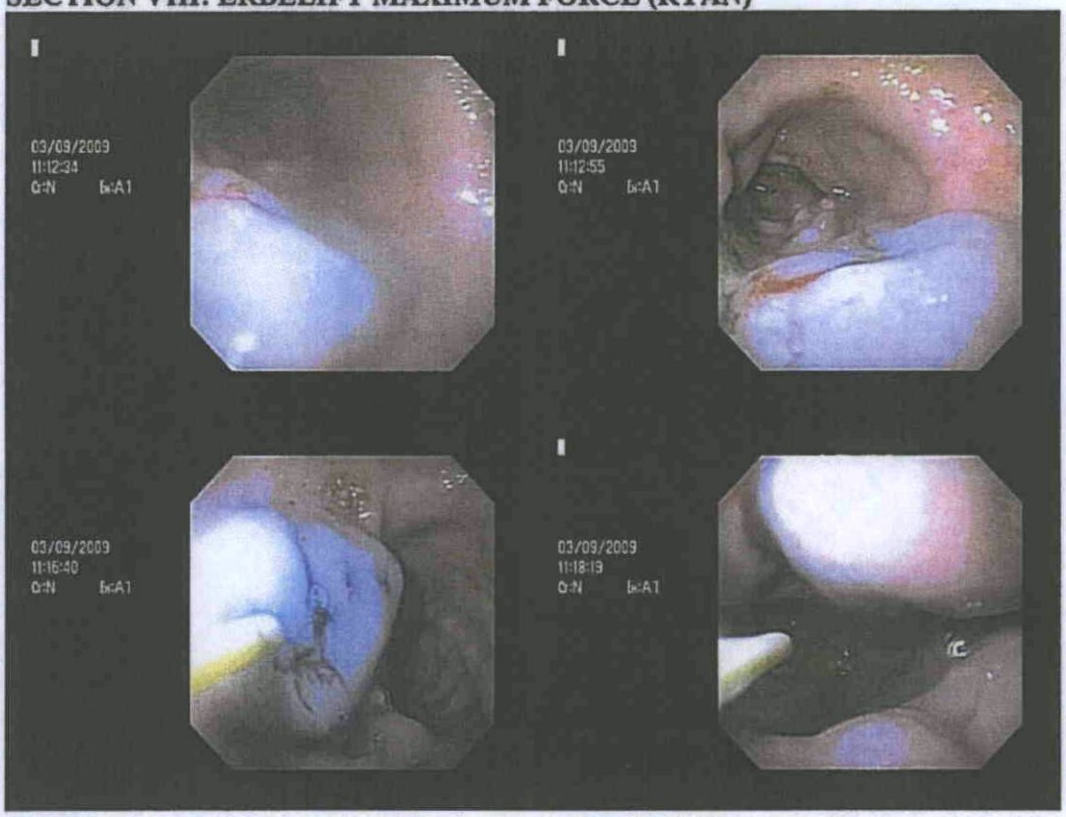
SECTION VIII: ERBELIFT MAXIMUM FORCE (RYAN)



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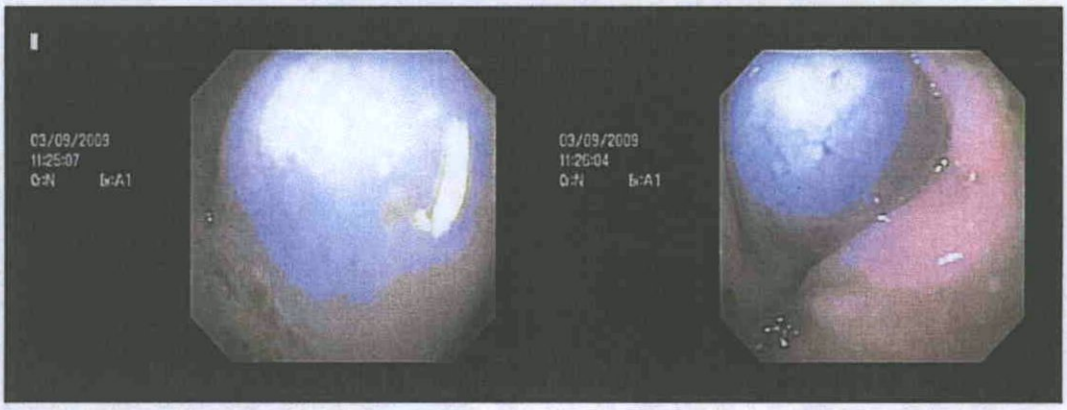
SECTION VIII: CARR-LOCKE NEEDLE MAXIMUM FORCE (RYAN)

SECTION IX: ERBELIFT MAXIMUM FORCE (DCL)



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ALL COLON SECTIONS

SECTIONS VIII AND IX NOT SHOWN

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