DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 24, 2014

United States Endoscopy Group, Inc.
Sagar Pimpalwar
Regualatory Affairs Specialist
5976 Heisley Road
Mentor, OH 44060

Re: K140763
Trade/Device Name: Monofilament polypectomy snare
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: March 25, 2014
Received: March 27, 2014

Dear Sagar Pimpalwar,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140763

Device Name: Monofilament polypectomy snare

Indications for Use:

The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___
(21 CFR 801 Subpart C)

Herbert P. Lerner-S
2014.04.24 14:12:37 -04'00'

K140763

Special 510(k): Device Modification

FDA/CDRH/DCC
MAR 27 2014
RECEIVED

Date: March 25, 2014

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

Reference: US Endoscopy Multi Stage Snare, 510(k) K133513, December 20, 2013

Dear Madam/Sir:

US Endoscopy hereby submits this **Special 510(k): Device Modification** to request a modification for the US Endoscopy Multi Stage Snare cleared under 510(k) K133513 on December 20, 2013. This modification is being made to facilitate the device to be used to resect flat polyps within the gastrointestinal tract. The modified device will be referred to as the Monofilament polypectomy snare in this submission. The US Endoscopy polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during gastrointestinal (GI) endoscopic procedures. US Endoscopy believes the modifications are eligible for the Special 510(k) process because the modified device has the same intended use and fundamental scientific technology as the predicate device.

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

US Endoscopy has submitted the required Premarket Notification review fees as required by the FDA. The payment identification number associated with this submission is MD6074426-956733 A copy of the User Fee Cover Sheet is included with this submission package.

The information included in this Premarket notification is detailed in nature. US Endoscopy considers the information to be confidential and believes the information qualifies for protection as per 21 CFR 807.95. Consequently, US Endoscopy requests the right to review and redact all confidential and proprietary information prior to it being released to any third party.

This Special 510(k) Premarket Notification is submitted in duplicate: a paper copy and a CD containing an electronic copy.

The eCopy is an exact duplicate of the paper copy

Please contact me if you have any questions. I can be reached by phone at 440-358-6265, fax at 440-639-6258, or by email at spimpalwar@usendoscopy.com

Sincerely,

Sagar D. Pimpalwar

Sagar Pimpalwar
Regulatory Affairs Specialist

Contains Nonbinding Recommendations

Acceptance Checklist
For Special 510 (k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review

510(k) Number: _____ **Date Received By DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Special 510(k) Criteria **The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.**			
	Yes	**No**	**Page No**
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.			Cover Letter
Comments:			
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).			**04,30, 33**
Comments:			
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).			**40**
Comments:			
4. The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30 (g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*			**33-38**
Comments:			

Does the submission meet all 4 criteria above?

- ☐ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

Organizational Elements

Failure to include these items along generally should not result in an RTA designation

	Yes	No	Page No
a. Submission contains Table of Contents			TOC
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)			
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).*	☐	☐	
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☐	☐	Cover Letter & page 2

Elements of a Complete Submission (RTA items) (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No	Page No
A	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☐			
		Comments:					
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):				☐	02-06
		a	Device trade name or proprietary name	☐		☐	04
		b	Device Common name	☐		☐	04
		c	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐		☐	04
		Comments:					

Elements of a Complete Submission (RTA items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page No**
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☐		☐	**30**
		Comments:					
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		☐		☐	**31**
		a	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	☐	
		b	Statement contains all elements per 21 CFR 807.93	☐		☐	
		Comments:					
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present, and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		☐		☐	**32**
		Comments:					
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*		☐	☐	☐	
		Comments:					
	7.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. *There should be a completed form for each referenced national or*		☐	☐	☐	**09-29**
Elements of a Complete Submission (RTA items)							

(21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page No**
		international standard.Select "N/A" only if submission does not reference any standards.					
		Comments:					
	8.	The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion.* *Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*			☐		☐	**04**
		a	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*	☐		☐	
Elements of a Complete Submission (RTA items)							

(21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**	**Page No**
		Comments:						
B	**Device Description**							
	9.	a	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		☐	☐	☐	
		b	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*		☐	☐	☐	**34-38**
		Comments:						
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:						**34-36**
		a	A description of the principle of operation and mechanism of action for achieving the intended effect.		☐		☐	**34**
		b	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device		☐		☐	**35-36**
Elements of a Complete Submission (RTA items)								

(21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page No**
			Interacts with patient.				
		c	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☐	☐	☐	
		Comments:					
	11.	A description of all device modification(s) including rationale for each modification.		☐		☐	**37-38**
		Comments:					
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the sponsor provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		☐	☐	☐	**34-36**
		Comments:					
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐		
		a	Submission includes a list of all components and accessories to be marketed with the subject device	☐		☐	**34**
		b	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been*	☐	☐	☐	**34**
Elements of a Complete Submission (RTA items)							

(21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page No**
			previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.				
		c	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.*	☐	☐	☐	
		Comments:					
C	**Substantial Equivalence Discussion**						
	14.	Submitter has identified a predicate(s) device					
		a	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationand Guidan ce/ComplianceActivities/ucm072746.htm).*	☐		☐	**33**
		b	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☐		☐	
		Comments:					
	15.	Submission includes a comparison of the following for the predicate(s) and subject device					**35-36**
		a	Indications for use	☐		☐	**35-36**
		b	Technology, including features, materials, and principles of operation	☐		☐	**35-36**
		Comments:					

Elements of a Complete Submission (RTA items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**	**Page No**
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance.*				☐		☐	**35-36**
		Comments:						
D	**Design Control**							
	17.	Design Control activities summary includes all of the following:						
		a	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis		☐		☐	**36**
		b	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.		☐		☐	**37-38**
		c	Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."*		☐		☐	**39**
			i	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.				
			ii	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30				

Elements of a Complete Submission (RTA items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**	**Page No**
			iii	Statement is signed by the individual responsible for these activities				
	Comments:							
E	**Proposed Labeling (See also 21 CFR part 801)**							
	18.	Submission includes proposed package labels, and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use			☐		☐	**41-45**
		a	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.		☐		☐	**33**
		Comments:						
	19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).			☐		☐	**33**
		Comments:						

Decision: **Accept:** _____ **Refuse to Accept:** _____

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ **Date:** _____

Supervisory Signature:_____ **Date:**_____

Special 510 (k) Premarket Notification

Monofilament Polypectomy Snare

United States Endoscopy Group, Inc.
5976 Heisley Road
Mentor, Ohio 44060

Special 510(k): Device Modification

Date: March 25, 2014

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

Reference: US Endoscopy Multi Stage Snare, 510(k) K133513, December 20, 2013

Dear Madam/Sir:

US Endoscopy hereby submits this **Special 510(k): Device Modification** to request a modification for the US Endoscopy Multi Stage Snare cleared under 510(k) K133513 on December 20, 2013. This modification is being made to facilitate the device to be used to resect flat polyps within the gastrointestinal tract. The modified device will be referred to as the Monofilament polypectomy snare in this submission. The US Endoscopy polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during gastrointestinal (GI) endoscopic procedures. US Endoscopy believes the modifications are eligible for the Special 510(k) process because the modified device has the same intended use and fundamental scientific technology as the predicate device.

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

US Endoscopy has submitted the required Premarket Notification review fees as required by the FDA. The payment identification number associated with this submission is [redacted] (b)(4) TS/CCI A copy of the User Fee Cover Sheet is included with this submission package.

The information included in this Premarket notification is detailed in nature. US Endoscopy considers the information to be confidential and believes the information qualifies for protection as per 21 CFR 807.95. Consequently, US Endoscopy requests the right to review and redact all confidential and proprietary information prior to it being released to any third party.

This Special 510(k) Premarket Notification is submitted in duplicate: a paper copy and a CD containing an electronic copy.

The eCopy is an exact duplicate of the paper copy

Please contact me if you have any questions. I can be reached by phone at 440-358-6265, fax at 440-639-6258, or by email at spimpalwar@usendoscopy.com

Sincerely,

Sagar Pimpalwar
Regulatory Affairs Specialist

United States Endoscopy Group, Inc. – Monofilament polypectomy snare
510(k) Premarket Notification – Special

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REGULATORY DOCUMENTATION

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
UNITED STATES ENDOSCOPY GROUP INC 5976 HEISLEY ROAD MENTOR OH 44060 US	Carroll Martin 2.1 E-MAIL ADDRESS cmartin@usendoscopy.com 2.2 TELEPHONE NUMBER (include Area code) 440-639-4494 629 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) Trade Secret 25-Mar-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

01

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/25/2014	(b)(4) Trade Secret	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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: United States Endoscopy	Establishment Registration Number *(if known)*: 1528319		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 440-358-6265		
Street Address: 5976 Heisley Road	FAX Number *(including area code)*: 440-639-6258		
City: Mentor	State / Province: Oh	ZIP/Postal Code: 44060	Country: USA
Contact Name: Sagar D. Pimpalwar			
Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: spimpalwar@usendoscopy.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 Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

02

PSC Publishing Services (301) 443-6740 EF

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

- [ ] New Device
- [ ] 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

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

- [ ] Response to FDA correspondence:

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

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

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

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

- [ ] 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

- [ ] Response 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)

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

- [x] Other Reason *(specify)*:

Modification to snare loop allows the end user to grasp and dissect flat and raised polyps

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FDI	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	K133513	1	Lariat Snare	1	US Endoscopy
2		2		2	
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 name

Monofilament Polypectomy Snare

	Trade or Proprietary or Model Name for This Device		Model Number
1	Monofilament Polypectomy Snare	1	711117
2		2	
3		3	
4		4	
5		5	

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

1 None	2 None	3 None	4 None	5 None	6 None
7 None	8 None	9 None	10 None	11 None	12 None

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FDI	876.4300	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Gastroenterology/Urology

Indications *(from labeling)*

The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4) Trade Secret Process

[redacted]

☐ 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 Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ 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 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	60601-1	AAMI/ANSI	Medical and electrical equipment part 1: General requirement for basic safety and essential performance	2005	1/14/2014
2	60601-2-2	IEC	Medical and electrical equipment part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and surgical accessories	2009	8/5//2013
3	60601-2-18	IEC	Medical equipment part 2-18: Particular requirements for the safety of endoscopic equipment	2009	8/5/2013
4	ISO 10993-1	International Organization for Standardization	Biological Evaluation of Medical Device Part 1: Evaluation and Testing with risk management process	2009	1/15/2013
5	ISO 10993-10	International Organization for Standardization	Biological Evaluation of Medical Devices Part 10 - Tests for Irritation and skin sensitization	2010	3/16/2012
6	ISO 10993-5	International Organization for Standardization	Biological Evaluation of medical Device part 5: Test for in vitro cytotoxicity	2009	5/5/2010
7	ISO 10993-11	International Organization for Standardization	Biological Evaluation of Medical device part 11: Test for Systemic toxicity	2010	03/16/2012

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1350 Piccard Drive, Room 400
Rockville, MD 20850

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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
US Endoscopy

2. Date of the Application/Submission Which This Certification Accompanies
03/25/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
5976 Heisley Road

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Mentor

State/Province/Region
OH

Country
USA

ZIP or Postal Code
44060

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 440-358-6265

(Fax): 440-639-6258

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)

Monofilament polypectomy snare, FDI under 21 CFR 876.4300, Class II device

Continuation Page for #5

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)*

If BLA was selected in item 6, provide Supplement Number

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 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 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 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.

Certification Statement / Information section continued on page 2

07

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

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. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

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. Name and Title of the Person who Signs Number 15

Name	Title
Sagar D. Pimpalwar	Regulatory Affairs Specialist

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* 5976 Heisley Road	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Mentor	State/Province/Region: OH
Country: USA	ZIP or Postal Code: 44060

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 440-358-6265

(Fax): 440-358-6258

14. Date of Certification

03/25/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

IEC 60601-1 Medical & electrical equipment part 1: General requirement for basic safety and essential performance

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-77	
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 tests? 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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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09

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 Medical & electrical equipment part 1: General requirement for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.9/8.3	Determination of applied parts and accessible parts	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
This"finger probe" test determines what is touchable in the product. this should be investigated to ensure there is no access to dangerous voltages in the product in normal use

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.8.3	Dielectric Strength	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
HF Surgical accessories strength is tested per clause 201.8.8.3.101 and 201.15.101.4 in IEC 60601-2-2

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.3	Surface, Corners and Edges	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Simple examination of rough surface, sharp corners and edges of ME equipment. These could result in unacceptable risk shall be avoided or covered

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 Medical & electrical equipment part I: General requirement for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15.3.4.1	Drop test hand-held ME equipment (drop test)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
After the test, any damage sustained that results in an unacceptable risk. No issues observed with the drop test for this product

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

IEC 60601-2-18 Medical electrical equipment pari 2: Particular requirements for' the safety of endoscopic equipment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#9-61	
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 tests? 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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-18 Medical electrical equipment pari 2: Particular requirements for' the safety of endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.11.101.2	Thermal and other hazards from interconnection condition with HF surgical	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
In order to protect, operator conductive parts of energized endoscope accessible to touch during normal use which are applied parts of HF surgical equipment, shall be isolated. Non conducting coatings, which cannot provide durable isolation, shall not be used

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

IEC 60601 -2 -2 Medical electrical equipment part 2-2:Particular requirements for basic safety & essential performance of high freq

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#9-62	
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.	☐	☒
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601 -2 -2 Medical electrical equipment part 2-2:Particular requirements for basic safety & essential performance of high freq

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.4.101	Neutral electrode monitoring circuit	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Not Conducted

DESCRIPTION
This test investigates a HF surgical generator's monitoring circuit for neutral electrode

JUSTIFICATION
This does to apply to HF surgical accessories

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.4.102	Neuromuscular Stimulation	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Not Conducted

DESCRIPTION
This test investigates a HF surgical generator's capacitance in the patient circuit

JUSTIFICATION
This does not apply to HF surgical accessories

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.7.3.101	Thermal effects of the HF leakage currents	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Not conducted

DESCRIPTION
This test is used to verify the generator has proper isolation or proper reference on the neutral connection

JUSTIFICATION
This setup in the standard shows an active accessory

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-2 Medical electrical equipment part 2-2:Particular requirements for basic safety & essential performance of high freq

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.8.3	Dielectric Strength	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
HF surgical accessories dielectric strength is tested per 201 .8.8.3. 101 and 201 .15.10 104

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.8.3.101	Active accessory insulation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Following saline preconditioning,applicable electrical testing shall be conducted HF leakage (201.8.8.3.102), HF dielectric strength (201.8.8.3.103) and mains frequency dielectric strength (201.8.8.3.104).Typical HF dielectric & leakage current tests for accessories

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.8.3.102	Active accessory HF leakage	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Insulation applied to cord for active accessories intended for monopolar application shall limit HF leakage current/leakage passing through external surface of insulation. In this test the limits are based on mechanical dimension and rated voltage.

JUSTIFICATION

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IEC 60601-2-2 Medical electrical equipment part 2-2:Particular requirements for basic safety & essential performance of high freq

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.8.3.103	Active accessory HF dielectric Strength	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
The insulation applied to active accessories shall be capable of withstanding HF voltage of 120% of the rated accessory voltage. Test voltage can be any sinusoidal voltage in the frequency range

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.8.3.104	Active accessory mains frequency dielectric strength	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Insulation applied to an active accessory including those portions of insulation having been tested at HF according to 201.8.8.3.103, shall withstand a DC or mains frequency peak voltage of 1000V greater than rated accessory voltage specified by manufacturer

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.10.4.2	Connection cords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
This test is for testing the cable from the accessory that plugs into the generator, ensure that flexing around the conncetor does not adversely affect the internal conductors

JUSTIFICATION

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SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-2 Medical electrical equipment part 2-2:Particular requirements for basic safety & essential performance of high freq

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8.10.4.101	Switch Sensors	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Not Conducted

DESCRIPTION
HF Surgical equipment and applicable associated equipment shall be provided with sensor requiring continuous activation in order to energize the active output terminal

JUSTIFICATION
The product do not incorporate switch sensors, this does not apply

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.11.1.1	Maximum temprature during normal use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
HF surgical equipment, set up to deliver it's rated output power into a resistive load using the electrode cable, is operated for 1 hr with duty cycle as specified y manufacturer but with operating times of at least 10s alternating with resting time not more that 30s

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological Evaluation of Medical Device part 1: Evaluation and Testing within a risk management process:2009

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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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: Use of International Standard ISO-10993 Biological Evaluation of Medical Device Part 1: Evaluation and t

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Device part 1: Evaluation and Testing within a risk management process:2009

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Table - Initial Evaluation test for consideration	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Testing only for limited duration (<24); surface device (breached or compromised surface)

DESCRIPTION
Cytotoxicity; Sensitization; Irritation or Intracutaneous and Systemic toxicity (acute)

JUSTIFICATION
According to the Standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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JUSTIFICATION

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☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological Evaluation of Medical Device Part 5: Test for in vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO 10993-Biological Evaluation of Medical Device part - 1 Evaluation and

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Device Part 5: Test for in vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Sample and Control preparation; General	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
The test performed on an extract of the test sample

DESCRIPTION
Extract of test article prepared with complete MEM

JUSTIFICATION
In accordance with standard; test article is not suitable to be used as test sample itself

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Preparation of liquid extracts of material	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Extraction vehicle was culture medium with serum; extraction for 24 ± 2hrs at 37±1°C

DESCRIPTION
Test conducted using an extract

JUSTIFICATION
As per the standard, culture medium with serum is preferred due to its ability to supports cellular growth

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Preparation of the material for direct-contact tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Test sample is tested by direct deposition

DESCRIPTION
Test sample administered in vitro to mouse fibroblast L929 cells

JUSTIFICATION
To evaluate the reactivity of the cells to the test sample

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Device Part 5: Test for in vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Cell Lines	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Cell lines obtained from American Type Culture Collection (ATCC)

JUSTIFICATION
As per standards, cell lines were obtained from recognized repositorie

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Culture Medium	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Culture medium with serum

DESCRIPTION
Culture medium was MEM

JUSTIFICATION
The culture medium meet the growth requirements of the selected cell lines

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Preparation of cell stock culture	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Test sample deposited directly on L929 cells

JUSTIFICATION
N/A

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Device Part 5: Test for in vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test Procedures	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Test on an original extract using cell monolayer, incubated at 37±1°C in air; used negetive and positive controls; cytotoxicity evaluated using qualitative method

DESCRIPTION
Tested an extract of the test material on L929 cells

JUSTIFICATION
Provides both qualitative and quantitative assessment of Cytotoxicity

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Test Report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
written test report

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Assesment of results	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Determination of Cytotoxicity

JUSTIFICATION
N/A

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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]

Biological Evaluation of Medical device - Part 10: Test for Irritation and Skin sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-174	
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 tests? 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: Use of International Standard ISO 10993-Biological Evaluation of the medical devices part 1- Evaluation a

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical device - Part 10: Test for Irritation and Skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General principles - Step-wise approach	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
In vivo animal tests

DESCRIPTION
Used 35 Hartley guinea pigs (Cavia porcellus);16 males and 19 females; weight/age: 35.3--491.0 grams/at least 26 days old (adult)

JUSTIFICATION
Historically, guinea pigs have been used in, and are generally regarded as the species of choice for laboratory identification of the skin allergens because the guidlines have no alternative (non-animal) methods.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Pretest Considerations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Test considerations

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Intracutaneous injections

DESCRIPTION
Three pairs of intradermal injections were made so that on each side of the midline there was on row of three injections each. injection 1 and 2 were given in close proximity to each other cranially. Injection 3 was located caudally

JUSTIFICATION
More rigorous test. Device can be used on compromised mucosal tissue.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Devices - Part 10: 2010 Tests for Irritation and Skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Skin sensitization test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Guinea pig maximization test (GPMT)

DESCRIPTION
An assessment is made of the potential for the material under test to produce skin sensitization in the guinea pig using the technique applied for single chemicals in the guinea pig maximization test.

JUSTIFICATION
Covers all stages of hypersensitivity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Key factors in interpretation of test results	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Test result interpretation

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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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]

Biological Evaluation of Medical Devices - Part 11: 2006 Tests for Systemic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
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 tests? 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: Use of International Standard ISO 10993-Biological Evaluation of Medical Devices Part 1-Evaluation an

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological Evaluation of Medical Devices - Part 11: 2006 Tests for Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General considerations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
20 Albino Swiss Mice (Mus musculus) used; 5 animals were injected with either the test article extracts or control article extract; single dosage used.

DESCRIPTION
General information

JUSTIFICATION
Historically, mice have been used in systemic safety evaluation studies because the guidelines have no alternative (non-animal) methods.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Repeated exposure systemic toxicity (subacute, subchronic and chronic syste)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

DESCRIPTION
Evaluation of testing

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity (subacute, subchronic and chronic syste)	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
Test device is a single-use device

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INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Monofilament polypectomy snare

Indications for Use:

The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___
(21 CFR 801 Subpart C)

PREMARKET NOTIFICATION 510(K) STATEMENT
(As Required by 21 CFR 807.93)

I certify that, in my capacity as the Regulatory Affairs Specialist of United States Endoscopy Group, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse, safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Sagar. D. Pimpalwar

Sagar Pimpalwar
Regulatory Affairs Specialist

Date: 3/25/14

_____

*(Premarket Notification [510(k)] Number)

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(k), I certify in my capacity as Regulatory Affairs Specialist for United States Endoscopy Group, Inc., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Sagar A. Pimpalwar

Sagar Pimpalwar
Regulatory Affairs Specialist

Date: 3/25/14

_____
*(Premarket Notification [510(k)] Number)

SPECIAL 510K DOCUMENTS

Special 510 (k) Information

Device Name The device trade name and common/classification name is:

Device Trade Name: US Endoscopy Monofilament polypectomy snare

Common/ Classification Name: Flexible, Snare

Manufacturer: United States Endoscopy Group, Inc.

Address and Registration
5976 Heisley Road
Mentor, Ohio 44060
Registration #: 1528319

Device Class Flexible snares have been classified as Class II, 876.4300 / FDI. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act.

Predicate Device Information The predicate device is the US Endoscopy Multi Stage snare, cleared under 510(k) number K133513 on December 20, 2013.

Labeling and Intended Use

Instructions for Use and draft labels can be found on pages 41-45

The changes to the labeling and Instructions for Use are as follows:

Labels:

- Change the product number from 00711119 to 00711117 (Highlighted)
- Change the name to reflect Monofilament polypectomy snare (Highlighted)
- Device picture with dimensions (Highlighted)

Instructions for Use:

- Revised IFU to indicate Monofilament polypectomy snare (Highlighted)
- Change the product number from 00711119 to 00711117 (Highlighted)

Intended Use

The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures. This is the same intended use as specified in the device IFU and the cleared 510(k) under K133513, December 20, 2013, and this intended use has not changed as a result of the modifications.

The Indications for Use Statement can be found on the page 30

Device Description

The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.

The device consists of a handle, catheter, finger ring, hypo tube, heat shrink, cautery connection, drive cable, connector and snare loop. The device is actuated using the finger rings to deploy and retract the snare loop. The cautery connection is used to connect the device to an electrosurgical generator via an active cord for delivery of electrosurgical current to the snare loop to aid in cutting the polyp and cauterizing the polyp removal site (b)(4) Trade Secret Process

(b)(4) Trade Secret Process

When deployed, the snare loop forms a diamond shape.

(b)(4) Trade Secret Process

Substantial Equivalence

The modified US Endoscopy Multi-Stage snare (Monofilament polypectomy snare) as compared to the original Multi-Stage snare:

SUBSTANTIAL EQUIVALENCE TABLE		
Features	**US Endoscopy Predicate device (Multi-Stage snare)**	**Monofilament polypectomy snare**
Intended/Indications For Use	The US Endoscopy Multi-Stage snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.	The US Endoscopy Monofilament polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.
510 (k) Clearance	K133513	TBD
Date Cleared	12/20/2013	TBD
Target Population	Patients undergoing polypectomy	Patients undergoing polypectomy
Anatomical Sites	GI track (upper and lower)	GI track (upper and lower)
Where used (e.g. Hospital, home, etc.)	Hospitals/Surgery Center	Hospitals/Surgery Center
Energy used and/or delivered	Monopolar radio frequency current	Monopolar radio frequency current
Design (e.g. Overall construction, length, width, etc.)	Handle, finger rings, catheter, drive cable and snare loop Device Length: 2300 mm Sheath diameter : 2.4mm Snare loop width: ≈ 3cm wide fully deployed and it offers three different stages/ shapes (oval, hex and diamond) Snare wire thickness: 0.018 inches Snare loop and drive cable connection: weld	Handle, finger rings, catheter, drive cable and snare loop Device length: 2300 mm Sheath diameter: 2.4 mm Snare loop width : ≈ 1.2 cm wide fully deployed Shapes: It offers only diamond shape Snare wire thickness: 0.008 x 0.015 inches. This snare wire is rectangular in shape Snare loop and drive cable connection: Hypo crimp connector
Materials/Vendors	(b)(4) Trade Secret Process [redacted]	
Principle of operation	Stainless steel cable transection via Monopolar current and actuation of snare loop by mechanical means	Stainless steel cable transection via Monopolar current and actuation of snare loop by mechanical means
Sterile/Non-sterile	Sterile	Sterile
Sterilization Method	EtO	EtO
Sterility Assurance level	10^{-6}	10^{-6}

SUBSTANTIAL EQUIVALENCE TABLE		
Features	**US Endoscopy Predicate device (Multi-Stage snare)**	**Monofilament polypectomy snare**
Electrical	Monopolar Energy	Monopolar Energy
Method of Application	Manual	Manual
Usage Period	Single use	Single use
Compatibility with other devices	Flexible endoscopes and active cord fit various types of connector	Flexible endoscopes and active cord fit various types of connector

The modified device shares the same intended use, fundamental technological characteristics, design and operating principle as the predicate. Testing performed on each modification demonstrates that these changes, both individually and cumulatively, do not have a significant effect on the safety and effectiveness of the device, do not raise different questions of safety and effectiveness than the predicate device and verifies the Monofilament polypectomy snare performs the same as the predicate.

In summary, the modified snare described in this submission is, in US Endoscopy's opinion, substantially equivalent to the predicate device.

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modification(s) was performed in accordance with ISO 14971:2012. The design verification tests that were performed as a result of this risk analysis assessment are listed in following Table:

TABLE – Design Control Activities Summary

Device Modification	Reason for Modification	Risk/Hazard	Mitigation	Verification Activity	Acceptance criteria	Verification Result
1. Twisted Snare loop wire (Monofilament)	1. To allow a physician to grasp and dissect flat and raised polyps	1. Inability to grasp and dissect polyps	1. Twisted loop wire	1. Using 5 devices per lot from three different lot (15 total devices) of Monofilament polypectomy snare were tested, each device by resecting 3 flat and 1 raised polyp	1. The Monofilament polypectomy snare must resect minimum of 3 flat and 1 raised polyps	Pass
		2. Transmural Burns/ electrical burns	1. Electrical testing	1. Conduct testing in accordance with • IEC 60601-1 • IEC 60601-2-2 • IEC 60601-2-18	Pass all relevant aspects of **IEC 60601-1** • Max temperature during normal use (particular conditions) clause 11.1.1. Follow test parameters as detailed in 201.11.1.1 in IEC 60601-2-2 • Determination of applied parts and accessible parts : clause 5.9 & 5.83 • Dielectric Strength (per 60601-2-2 conditions) • Surface, Corners and Edges clause 9.3 • Drop test hand-held ME equipment (drop test) 15.3.4.1 **IEC60601-2-2** • Maximum temperature during normal use clause: 201.11.1.1. Follow test parameters as detailed in 201.11.1.1 in IEC 60601-2-2 and test set up and requirements as detailed in 11.1of IEC 60601-1 • High Frequency leakage current clause: 201.8.8.3.102 • High frequency dielectric withstands clause: 201.8.8.3.103 • Mains frequency dielectric withstand clause: 20.8.8.3.104 **IEC60601-2-18** • Maximum temperature during normal use: clause 11.1.1 follow test parameters as detailed in 201.11.1.1 in IEC 60601-2-2 and test set up and requirements as detailed in 11.1 of IEC 60601-1 • Capacitive coupled HF leakage current : clause 201.11.101.2	Pass
		3. Biocompatibility	1. Testing in accordance with ISO 10993-5; 10; -11	1. Conduct testing in accordance with standard	1. Meet standard requirements	Pass

2. Torsion spring	1. To open snare loop on deployment in multiple deploy and retraction cycle	1. Failure of snare to open repeatedly	1. Verification by functional testing	1. Total 15 device (5 per lot) from three different lots were tested, each device was deployed and retracted for 10 times in torturous configuration	1. The snare must open on multiple deployments	Pass
3. Crimp Connector	1. To secure snare loop and drive cable connection	1. Detachment of snare loop	1. Verification by Structural integrity testing	1. A minimum of 5 devices from three different lots (15 total devices) were subjected to tensile testing. Devices were tested by gripping opposing ends in a fixture and exerting an axial pull until structural failure occurred	(b)(4) Trade Secret Process	Pass

The test methods used are the same as those submitted in the original submission.

A declaration of conformity with design controls is included on page 39

510(k) Summary /Statement

A 510(k) statement for the modification to the US Endoscopy Multi-stage snare is included on page 31

Truthful and Accuracy Statement

A certification of the truthfulness and accuracy of this submission for the modification to the US Endoscopy Multi-Stage snare is provided on page 32

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification(s) were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Name: Dagne D. Rimpalewar

Date: 3/25/14

Title: Regulatory Affairs specialist

Company: US Endoscopy

Manufacturing Facility

The facility where this device was designed, United States Endoscopy Group, Inc., 5976 Heisley Road, Mentor, Ohio 44060, Registration Number 1528319, is in conformance with the design control requirements as specified in 21 CFR 820.30 and these records are available for review.

Name: Carrall Montes

Date: 3/25/14

Title: Director, Regulatory Affairs

Company: US Endoscopy

Special 510 (k) Fundamental Technology Statement

I certify that the modifications made that are the subject of this Special 510(k) have not altered the fundamental technology of the predicate device, US Endoscopy Multi-Stage snare, cleared under 510(k) number K133513 on December 20, 2013.

Dagar D. Pimpalwar
Name

3/25/14
Date

Regulatory Affairs Specialist
Title

US Endoscopy
Company

PROPOSED LABELING

US endoscopy

Monofilament polypectomy snare

Reorder No. 00711117

INSTRUCTIONS FOR USE

US endoscopy

listening... and delivering solutions

5976 Heisley Road
Mentor, OH 44060 USA

phone +1 440 / 639.4494

fax +1 440 / 639.4495

email global@usendoscopy.com

www.usendoscopy.com

CE 0086

00732015 Rev. A

This device is not made with natural rubber latex.

Intended Use:
The US Endoscopy Monofilament Polypectomy snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during Gastrointestinal (GI) endoscopic procedures.

Description	Product #	Sheath Diameter	Sheath Length	Active Cord Style
Monofilament Polypectomy snare	00711117	2.4mm	230 cm	Olympus Style

Warnings and Precautions:

- Consult the medical literature relative to techniques, complications and hazards prior to the performance of any endoscopic procedure.
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques in polypectomy.
- Use of a snare should not be attempted unless proficiency in technique has been developed by the clinician.
- Endoscopic polypectomy with diathermic snares should not be performed without a thorough understanding of the principles of diathermic energy.
- Consult the electrosurgical generator manufacturer's instructions for use for proper settings and use of the generator.
- In order to ensure that the insulating properties of the diathermic snares are not compromised, do not exceed the maximum rated peak voltage of 2500 for cut mode and 2500 for coagulation mode.
- US Endoscopy did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- 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.
- These devices are compatible with an endoscope accessory channel of 2.8mm or larger.
- The following conditions may not allow the MultiStage Snare device to function properly:
  (1) advancing the handle to the open position with too much speed or force,
  (2) attempting to pass or open the device in an extremely articulated endoscope,
  (3) attempting to actuate the device in an extremely coiled position and/or
  (4) actuating the device when the handle is at an acute angle in relation to the sheath.
- Short strokes, 1"-1.5" (2.5cm – 3.8cm) in length, are recommended throughout device passage to avoid sheath kinking.

Contraindications:

- Contraindications include, but are not limited to, those specific to any endoscopic procedure.
- Coagulopathy
- Poor bowel prep
- Uncooperative patient

Directions for Use:

1. Prior to clinical use, inspect and familiarize yourself with the device. If there is evidence of damage, **do not use this product and contact your local Product Specialist.**
2. Remove the device from the package and uncoil the entire device and drape in a "U" shaped configuration, holding the proximal end in one hand and the distal sheath in the opposite hand.
3. Move the finger rings back and forth to confirm that the snare loop opens and closes smoothly.
4. Ensure the snare loop is fully retracted into the sheath prior to insertion into the endoscope.
5. Ensure that the device is compatible with an endoscope channel of 2.8mm or larger before insertion.
6. Position patient return electrode and connect to electrosurgical unit following instructions from the electrosurgical unit manufacturer.
7. Attach the respective Olympus style active cord to the snare's diathermic handle connection prior to excision of polyps or tissue.
8. The electrosurgical unit should be set to the proper setting that will allow resection with controlled hemostasis.

   Caution: In order to ensure that the insulating properties of the diathermic snares are not compromised, do not exceed the maximum rated peak voltage of 2500 for cut mode and 2500 for coagulation mode.

9. When the polyp or tissue has been endoscopically visualized, resect the polyp using proper endoscopic technique.
10. Once the polyp(s) has been resected, the polyp(s) or tissue should be removed and prepared according to standard technique for histologic evaluation.

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: March 25, 2014

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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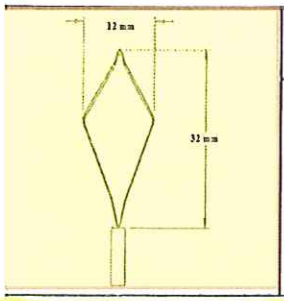
Made in the U.S.A.

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	
Lot	LOT	Do Not Re-Sterilize	Sterile
Date of Manufacture		EC REP Authorized Representative in the European Community	
Length		Read instructions prior to using this product	
For use with Microvasive active Cord	MICROVASIVE	For use with Olympus active cord	OLYMPUS
Store at controlled room temperature	15-25°C	Product contains Phthalates	PHT
Inside Diameter (I.D.)		Outside Diameter (O.D.)	
Discard within 24 hours after opening package	> 24 Hours	**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.	

Do not use if packaging or product damage is evident. For sterile products only, contents are sterile if package is unopened and undamaged.

US endoscopy
listening... and delivering solutions©
5976 Heisley Road
Mentor, Ohio 44060
phone (1) 440 / 639-4494
fax (1) 440 / 639-4495
customer service (1) 800 / 769-8226
www.usendoscopy.com
A subsidiary of STERIS Corporation

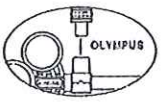


REF 00711117

10 Contents

230 cm

Ø 2.4 mm



LOT 1234567
Lot Number

Use By 2015-03

Date of Manufacture 2014-03

Monofilament polypectomy snare

CE 0086

Single Use Only

STERILE EO — Sterilized with Ethylene Oxide

Read Instructions prior to using this product

Do Not Use if Damaged

15-25°C — Store at controlled room temperature

Do not re-sterilize

EC REP — Diagmed Healthcare Ltd.
Lumley Close, Thirsk Industrial Park
Thirsk, North Yorkshire, YO7 3TD, U.K.
Tel: 01845 526660 Fax: 01845 522199

Rx Only (U.S.A.)
MADE IN U.S.A.

See package insert for explanation of symbols.

+H788007111171E

+$$900010031512345 67E8

US endoscopy

REF 00711117

10 Contents

Monofilament polypectomy snare

LOT 1234567
Lot Number

Use By 2015-03

731175 Rev B

www.usendoscopy.com 00732017 Rev. A 0001

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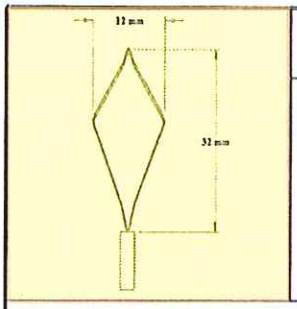
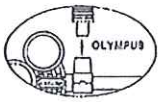


REF 00711117

1 Contents

230 cm

Ø 2.4 mm



LOT 1234567
Lot Number

Use By 2015-03

Date of Manufacture 2014-03

Monofilament polypectomy snare

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Lumley Close, Thirsk Industrial Park
Thirsk, North Yorkshire, YO7 3TD, U.K.
Tel: 01845 526660 Fax: 01845 522199

Rx Only (U.S.A.)
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