

K111495

JUL 19 2011

ATTACHMENT F: 510(k) Summary

SPONSOR: Wilson-Cook Medical, Inc. /Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105

CONTACT/SUBMITTER: Marge Walls-Walker
Senior Regulatory Specialist: Engineering
[336] 744-0157 Ex. 6290

DATE OF SUBMISSION: May 26, 2011

DEVICE: Gastroenterology Injection Needle

Trade Name: Cook GI Endoscopic Injection Gel Kit
Common Name: GI Endoscopic Injection Needle
Classification: GI/GU Injection Needle, Class II FBK
21 CFR § 876.1500

PREDICATE DEVICES: US Endoscopy Dual Lumen Injector Needle Snare
(k040961)
Cook Endoscopic Ultra Ultrasound Needle
(k083330)

INTENDED USE: This device is indicated for sub mucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device

DEVICE DESCRIPTION: The proposed Cook Device is assembled by the end user from three component pieces: a handle with a threaded piston and directional arrow, a sterile needle cannula with an attached pressure gauge to track pressure in the event of needle kinks/bends in the tortuous GI anatomy and a sterile 10 cc syringe filled with a mixture of sterile water and sodium CMC. Blue colorant may or may not be added to enhance endoscopic visibility. After creation of a starter bleb below affected tissue, the gel is then injected into the starter bleb. The bleb will then stay elevated from the muscle layer to allow for endoscopic dissection or resection with a separately supplied endoscopic electrosurgical device. After excision and retrieval of affected tissue, the bleb will dissolve and pass out of the body naturally.

COMPARISON OF CHARACTERISTICS:

We believe the proposed device to be substantially equivalent to the named predicates in terms of Intended Use, Indications for Use, performance characteristics tested, needle gauge, principle of operation and biocompatibility. No electrosurgical instrument is provided with the subject device to allow for the excision, but the removal of the bleb can be accomplished using one of the many existing technologies available.

PERFORMANCE DATA:

Pre-clinical testing verified the biological safety of the injection media and validated the performance capabilities of the GI Endoscopic Injection Gel Kit to meet its design criteria through a series of bench and animal testing. The IFU suggests a preliminary injection of saline to begin the bleb to reduce the inherent risk of all injection needles for perforation/injection into the muscularis. The subject device is meant to complement existing technologies for excision of GI tract tissue by creation of a visible bleb using a viscous injectate that is easily available, and effective. The viscosity of the subject gel overcomes the limitation of injection of saline and other low viscosity materials with respect to time the bleb remains elevated from the muscularis and other mechanical mucosal separation techniques that may result in muscle layer involvement.



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

Ms. Marge Walls-Walker
Senior Regulatory Affairs Specialist
Wilson Cook Medical, Inc. / Cook Endoscopy
4900 Bethania Station Rd
WINSTON-SALEM NC 27105

JUL 19 2011

Re: K111495

Trade/Device Name: Cook GI Endoscopic Injection Gel Kit
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: May 26, 2011
Received: May 31, 2011

Dear Ms. Walker:

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

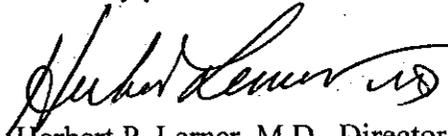
Page 2

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

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

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

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): k111495

Device Name: Cook GI Endoscopic Injection Gel Kit

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

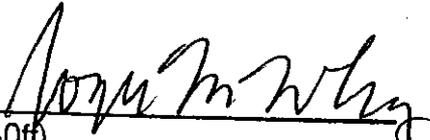
AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number k111495

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K 111 495 / AH

To: Division Director: GU / DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [Signature]

Date: AUG 22 / 11

8/30
DCC

DRGUD
LO 8/30/2011
NORF

K111495/a1



RECEIVED DMC
JUL 20 2011
Received

K-25

COOK ENDOSCOPY
4900 BETHANIA STATION ROAD
WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

July 18, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Premarket Notification for a Traditional 510(k): k111495: Cook GI Endoscopic Injection Gel Kit

Dear Sir or Madame,

On 7.18.2011, Dr. Hector Herrera, M.D., MPH Medical Officer from the FDA Office of Device Evaluation, ULDB, contacted me via phone to request that I forward a revised "Indications for Use Form" to his attention via e-mail.

I returned all requested information to Dr. Herrera electronically on 7.18.2011 and am herewith enclosing paper copies of the same for inclusion in the docket. Please route these to Dr. Herrera at your earliest possible convenience.

Best Regards,

Marge Walls-Walker
Senior Regulatory Specialist: Engineering

Indications for Use Form

Indications for Use

510(k) Number (if known): k111495

Device Name: Cook GI Endoscopic Injection Gel Kit

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Indications for Use Form

Indications for Use

510(k) Number (if known): k111495

Device Name: Cook GI Endoscopic Injection Gel Kit

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s):

K111495/02

To: Division Director:

GU / DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm).

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by:

[Signature]

Date:

AUG 22/11

8/30
PCC

DRGUD
W 8/30/2011
NR

K-11495/az



COOK ENDOSCOPY
4900 BETHANIA STATION ROAD
WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

July 15, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

K-9
FDA CDRH DMC
JUL 20 2011
Received

RE: Premarket Notification for a Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

Dear Sir or Madame,

On 7.12.2011, Dr. Hector Herrera, M.D., MPH Medical Officer from the FDA Office of Device Evaluation, ULDB, contacted me via phone to request that I forward a Kit Certification according to the FDA guidance on Convenience Kits and FDA Form 3654, Standards Data Report(s) for standards referenced in the Appendices to the original submission.

I returned all requested information to Dr. Herrera electronically by 7.14.2011 and am herewith enclosing paper copies of the same for inclusion in the docket. Please route these to Dr. Herrera at your earliest possible convenience.

Best Regards,

Marge Walls-Walker
Senior Regulatory Specialist: Engineering

July 13, 2011

Kit Certification for 510(k)s

"If you cannot make the above referenced statement in the second paragraph for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.)."

Kit Component Certification

Component	Clearance/Approval or Pre-Amendment*	Further Processing for Subject Device
Handle	Yes, k 042691*	Repackage/relabel, non sterile
Syringe	Yes, k 042691*	Addition of silicone O-ring and Teflon tape proximal end of plunger, fill with gel, repackage, relabel, sterilize with moist heat vs. EO
Injection Needle	Yes, k 083330*	Minor modification to handle to create gauge interface. EO Sterilized in identical cycle
Gauge	No	Repackage, relabel, sterilize
Sodium Carboxymethylcellulose	Yes, k060815*, P040047, Exempt per 872.3140 21 CFR 182.1745	Mixed in-house with FD&C #2, 100% viscosity verification per batch, syringe fill, package, label and sterilize with moist heat (as sterilized in referenced k). In this application the gel is not intended as an implant or to be resorbable.
FD&C Blue No. 2	Yes, k052900* 21 CFR 82.102	

*Cleared Intended Uses are detailed below:

K 083330: Injection Needle: This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract

K 042691: Syringe and Handle Components: Vertefix™ Radiopaque Bone Cement is indicated for the fixation of vertebral compression fractures during a vertebroplasty procedure.

K 060815: Carboxymethylcellulose: BioForm's Juliesse is indicated as a resorbable implant material to aid in surgical reconstruction as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months.

K052900: FD&C Blue #2: Quil® non-absorbable nylon barbed sutures are indicated for soft tissue approximation excluding closure of the epidermis.

Marge Walls-Walker 7.13.11

Marge Walls-Walker 7.13.2011

July 13, 2011

Kit Certification for 510(k)s

"If you cannot make the above referenced statement in the second paragraph for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.)."

Kit Component Certification

Component	Clearance/Approval or Pre-Amendment*	Further Processing for Subject Device
Handle	Yes, k 042691*	Repackage/relabel, non sterile
Syringe	Yes, k 042691*	Addition of silicone O-ring and Teflon tape proximal end of plunger, fill with gel, repackage, relabel, sterilize with moist heat vs. EO
Injection Needle	Yes, k 083330*	Minor modification to handle to create gauge interface. EO Sterilized in identical cycle
Gauge	No	Repackage, relabel, sterilize
Sodium Carboxymethylcellulose	Yes, k060815*, P040047, Exempt per 872.3140 21 CFR 182.1745	Mixed in-house with FD&C #2, 100% viscosity verification per batch, syringe fill, package, label and sterilize with moist heat (as sterilized in referenced k). In this application the gel is not intended as an implant or to be resorbable.
FD&C Blue No. 2	Yes, k052900* 21 CFR 82.102	

*Cleared Intended Uses are detailed below:

K 083330: Injection Needle: This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract

K 042691: Syringe and Handle Components: Vertefix™ Radiopaque Bone Cement is indicated for the fixation of vertebral compression fractures during a vertebroplasty procedure.

K 060815: Carboxymethylcellulose: BioForm's Juliesse is indicated as a resorbable implant material to aid in surgical reconstruction as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months.

K052900: FD&C Blue #2: Quill® non-absorbable nylon barbed sutures are indicated for soft tissue approximation excluding closure of the epidermis.

Marge Walls-Walker 7.13.11

Marge Walls-Walker 7.13.2011

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

ISO 14971:2007 Medical devices-Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-40

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>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 14971:2007 Medical devices-Application of risk management to medical devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex I	SECTION TITLE Guidance on risk analysis process for biological hazards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * All factors as identified in I.2.1: physical and chemical characteristics of the materials, history of use and human exposure data, existing toxicological and biological safety data on product/component materials and test procedures		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>* 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.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour 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:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: right; margin-right: 40px;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

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

ISO 14971:2007 Medical devices-Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-40

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>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 14971:2007 Medical devices-Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex I	Guidance on risk analysis process for biological hazards	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
All factors as identified in I.2.1: physical and chemical characteristics of the materials, history of use and human exposure data, existing toxicological and biological safety data on product/component materials and test procedures

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.

♦ 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-229

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>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Section 7, X2,X3	SECTION TITLE Accelerated Aging Planning	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Complete assembly aging Parameters: 38 days@55°C +/-2°C and <20% Relative Humidity. The RH value is a deviation from Annex 3 parameters.		
DESCRIPTION The third-party vendor has a default setting of <20% for all accelerated aging which exceeds recommendation in A3, but provides worst-case scenario for test parameter.		
JUSTIFICATION Temperature parameter was dictated by most limiting packaging/sealing configuration (pouch for moist heat sterilization) as recommended by the packaging vendor. Relative Humidity is default as set by aging vendor		
SECTION NUMBER Section 8	SECTION TITLE Post-Aging Testing Guidance	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Functional Testing post accelerated aging		
DESCRIPTION Post Accelerated Age Testing of assembled device detailed in Section 7.2.2 of the submission.		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour 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:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: right;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-229

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)?
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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?
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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: _____

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>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</p>	<p>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.</p> <p>⁵ The supplemental information sheet (SIS) is <i>additional information</i> which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER Section 7, X2,X3	SECTION TITLE Accelerated Aging Planning	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
Option: Complete assembly aging Parameters: 38 days@55°C +/-2°C and <20% Relative Humidity. The RH value is a deviation from Annex 3 parameters.

DESCRIPTION
The third-party vendor has a default setting of <20% for all accelerated aging which exceeds recommendation in A3, but provides worst-case scenario for test parameter.

JUSTIFICATION
Temperature parameter was dictated by most limiting packaging/sealing configuration (pouch for moist heat sterilization) as recommended by the packaging vendor. Relative Humidity is default as set by aging vendor

SECTION NUMBER Section 8	SECTION TITLE Post-Aging Testing Guidance	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
Functional Testing post accelerated aging

DESCRIPTION
Post Accelerated Age Testing of assembled device detailed in SECTION 7.2.2 of the submission.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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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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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-1:2009 Biological evaluation of Medical Devices- Part 1: Eval and testing within a risk management system.

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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Does this standard include more than one option or selection of tests?
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Were deviations or adaptations made beyond what is specified in the FDA SIS?
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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: G95-1: Use of International Standard ISO 10993"Biological Evaluation of Medical Devices Pt 1:....."

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

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Please answer the following questions

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FDA Recognition number ³ #2-156

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Is there an FDA guidance ⁶ that is associated with this standard?
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Title of guidance: G95-1: Use of International Standard ISO 10993"Biological Evaluation of Medical Devices Pt 1:....."

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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10: Biological Eval of Med Dev-Part 10: Tests for Irritation and delayed-type sensitivity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-152

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)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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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?.....
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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: G95-1 "Use of International Standard ISO 10993, Biological Evaluation om Med Dev Part 1: Eval and Tes"

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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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10: Biological Eval of Med Dev-Part 10: Tests for Irritation and delayed-type sensitivity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-152

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If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: G95-1 "Use of International Standard ISO 10993, Biological Evaluation om Med Dev Part 1: Eval and Tes"

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5:2009 Biological eval.of Medical Devices- Part 5: Tests for in-vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #023 2-153

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).

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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: G95-1: Use of International Standard ISO 10993"Biological Evaluation of Medical Devices Pt 1:....."

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 ISO 10993-5:2009 Biological eval.of Medical Devices- Part 5: Tests for in-vitro cytotoxicity		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 8.2 , 8.5	SECTION TITLE Test on Extracts. Determination of cytotox. Introducer Components and Syring	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * IX MEM Elution		
DESCRIPTION Full tests reports attached as Annex in 510(k)		
JUSTIFICATION None needed, per standard recommendations and FDA recognition		
SECTION NUMBER 8.4.1, 8.4.2, 8.5	SECTION TITLE Tests by indirect contact: Agar diffusion, filter diffusion, determination of cyto	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Filtration followed by agarose overlay		
DESCRIPTION Full tests reports attached as Annex in 510(k)		
JUSTIFICATION Feasible test methodology for Carboxymethylcellulose		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5:2009 Biological eval.of Medical Devices- Part 5: Tests for in-vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #023 2-153
#11111

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-279

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4.0	SECTION TITLE Requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	-------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *
Option: 4.2,4.3,4.4.6.2: Device (Needle)categorized as limited exposure

DESCRIPTION
Completed simulated use extraction in similar device.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-279

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4.0	SECTION TITLE Requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
Option: 4.2,4.3,4.4.6.2: Device (Needle)categorized as limited exposure

DESCRIPTION
Completed simulated use extraction in similar device.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11135-1:2007 Sterilization of health care products:Ethylene Oxide-Part 1: Requirements for the development, validation and....

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1:2007 Sterilization of health care products:Ethylene Oxide-Part 1: Requirements for the development, validation and...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B.1.2(a)	Conservative determination of Lethal Rate of Sterilization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Half Cycle Approach

DESCRIPTION
3 consecutive cycles run resulting in total inactivation of BIs (10-6) to confirm minimum exposure time. Specified exposure time shall be 2X this minimum time. Cycle of short duration run from which survivors can be recovered to demonstrate adequacy.

JUSTIFICATION
None, the half cycle method was run in accordance with standard recommendations and TIR16, process development and performance qualification for ethylene oxide sterilization- Micorbiological aspects

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.3.2.5(b)	Validation:Performance Qualification	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Product was adopted to existing, validated cycle, no PQ performed for this component (needle)

DESCRIPTION
IQ and OQ previously performed for equipment that delivers same process parameters

JUSTIFICATION
Adopted per TIR 28, Product adoption and process equivalence for ethylene oxide sterilization.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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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>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 11135-1:2007 Sterilization of health care products:Ethylene Oxide-Part 1: Requirements for the development, validation and...		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex B.1.2(a)	SECTION TITLE Conservative determination of Lethal Rate of Sterilization	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Half Cycle Approach		
DESCRIPTION 3 consecutive cycles run resulting in total inactivation of BIs (10-6) to confirm minimum exposure time. Specified exposure time shall be 2X this minimum time. Cycle of short duration run from which survivors can be recovered to demonstrate adequacy.		
JUSTIFICATION None, the half cycle method was run in accordance with standard recommendations and TIR16, process development and performance qualification for ethylene oxide sterilization- Micorbiological aspects		
SECTION NUMBER 9.3.2.5(b)	SECTION TITLE Validation:Performance Qualification	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Product was adopted to existing, validated cycle, no PQ performed for this component (needle)		
DESCRIPTION IQ and OQ previously performed for equipment that delivers same process parameters		
JUSTIFICATION Adopted per TIR 28, Product adoption and process equivalence for ethylene oxide sterilization.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour 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:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: right;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

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

ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and rou

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-261

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>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and roui

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER Annex D	SECTION TITLE Conservative process definition based on inactivation of reference microorgani	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
Option: D2.2(a)Place biological indicators w/i the product at position(s) where sterilizing conditions are most difficult to achieve
Option: D3Partial cycle approach

DESCRIPTION
D.3 Expose load to sterilizing agent under conditions designed to deliver reduced level of treatment to the extent of inactivation of 10^6 microorganism on BI. Identified level of treatment repeated 3X.

JUSTIFICATION
Most suitable sterilization method for Carboxymethylcellulose

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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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Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

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ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and rou

Please answer the following questions

Yes No

Is this standard recognized by FDA?²

FDA Recognition number³ #14-261

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Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and routi

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex D	Conservative process definition based on inactivation of reference microorgani	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: D2.2(a)Place biological indicators w/i the product at position(s) where sterilizing conditions are most difficult to achieve
Option: D3Partial cycle approach

DESCRIPTION
D.3 Expose load to sterilizing agent under conditions designed to deliver reduced level of treatment to the extent of inactivation of 10^6 microorganism on BI. Identified level of treatment repeated 3X.

JUSTIFICATION
Most suitable sterilization method for Carboxymethylcellulose

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Rockville, MD 20850

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

Ms. Marge Walls-Walker
Senior Regulatory Affairs Specialist
Wilson Cook Medical, Inc. / Cook Endoscopy
4900 Bethania Station Rd
WINSTON-SALEM NC 27105

JUL 19 2011

Re: K111495
Trade/Device Name: Cook GI Endoscopic Injection Gel Kit
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: May 26, 2011
Received: May 31, 2011

Dear Ms. Walker:

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

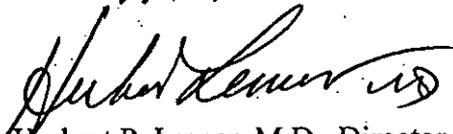
Page 2

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

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

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

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): k111495

Device Name: Cook GI Endoscopic Injection Gel Kit

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

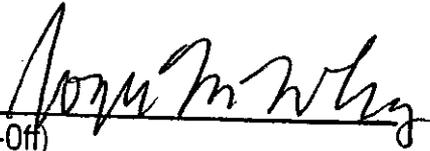
AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number k111495

K11495



COOK ENDOSCOPY
4900 BETHANIA STATION ROAD
WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

FDA CDRH DMC

JUN 15 2011

Received

Handwritten initials

6/14/2011

June 14, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Premarket Notification for a Traditional 510(k): k111495: Cook GI Endoscopic Injection Gel Kit

Dear Sir or Madam,

Enclosed, please find an electronic copy of the above 510(k) as requested by Dr. Hector Herrera via phone on 6.14.2011. Please forward this disc to Dr. Herrera as expediently as possible.

Cook considers its intent to market this product as confidential, commercial information and we request that it be considered as such by FDA. Information contained herein should not be made available through the Freedom of Information Act, except as required by law.

Should there be any questions pertaining to this submission, please do not hesitate to contact me.

Sincerely,

Marge Walls-Walker
Senior Regulatory Affairs Specialist: Engineering
Wilson-Cook Medical, Inc. /Cook Endoscopy
[336] 744-0157 x-6290
[336] 201-5024 FAX
marge.walls-walker@cookmedical.com



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 01, 2011

WILSON-COOK MEDICAL INC.
COOK ENDOSCOPY
4900 Bethania Station Rd
WINSTON-SALEM, NORTH CAROLINA 27105
ATTN: MARGE WALLS-WALKER

510k Number: K111495

Received: 5/31/2011

Product: COOK GI ENDOSCOPIC INJECTION G

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

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

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

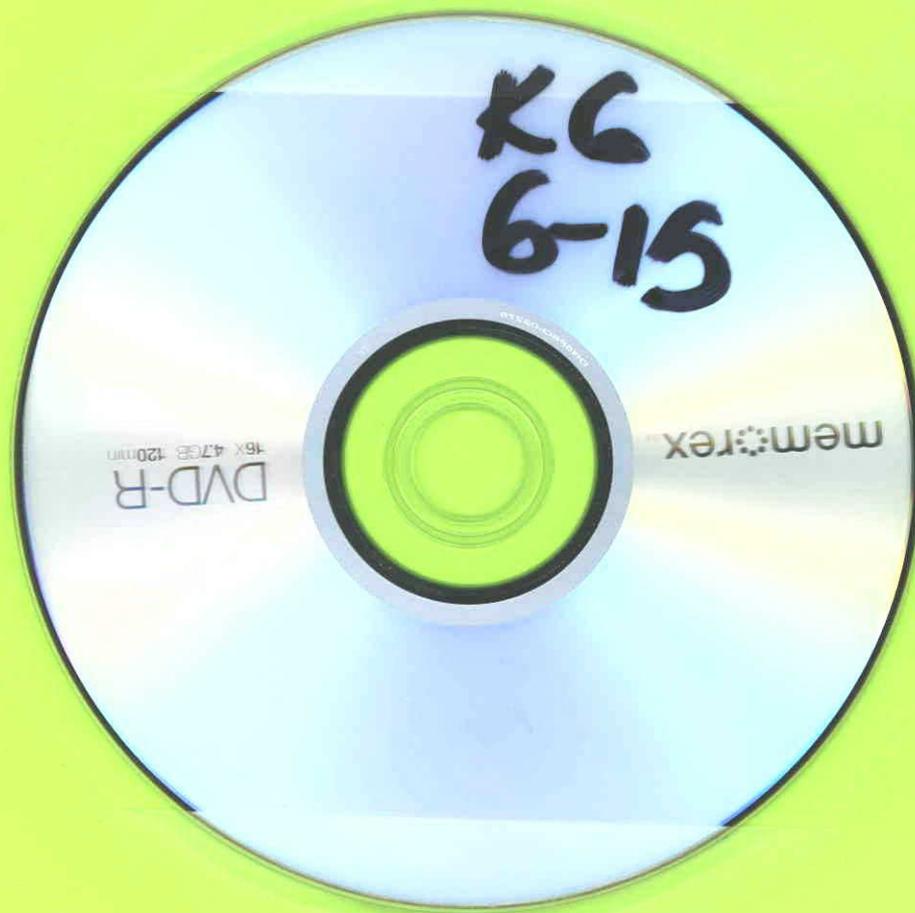
In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff





510K
K16
5-31
N

K11495

Form Approved: OMB No. 0910-511. 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) 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/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) WILSON COOK MEDICAL INC 4900 BETHANIA STATION ROAD WINSTON SALEM NC 27105 US		2. CONTACT NAME Marge Walls-Walker 2.1 E-MAIL ADDRESS marge.walls-walker@cookmedical.com 2.2 TELEPHONE NUMBER (include Area code) 336-744 0157 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 336-201	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)			
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/oc/mdufma)			
Select an application type:		3.1 Select a center	
<input checked="" type="checkbox"/> [X] Premarket notification(510(k)); except for third party		<input checked="" type="checkbox"/> [X] CDRH	
<input type="checkbox"/> [] 513(g) Request for Information		<input type="checkbox"/> [] CBER	
<input type="checkbox"/> [] Biologics License Application (BLA)		3.2 Select one of the types below	
<input type="checkbox"/> [] Premarket Approval Application (PMA)		<input checked="" type="checkbox"/> [X] Original Application	
<input type="checkbox"/> [] Modular PMA		Supplement Types:	
<input type="checkbox"/> [] Product Development Protocol (PDP)		<input type="checkbox"/> [] Efficacy (BLA)	
<input type="checkbox"/> [] Premarket Report (PMR)		<input type="checkbox"/> [] Panel Track (PMA, PMR, PDP)	
<input type="checkbox"/> [] Annual Fee for Periodic Reporting (APR)		<input type="checkbox"/> [] Real-Time (PMA, PMR, PDP)	
<input type="checkbox"/> [] 30-Day Notice		<input type="checkbox"/> [] 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)			
<input type="checkbox"/> [] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA		<input checked="" type="checkbox"/> [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? (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.)			
<input checked="" type="checkbox"/> [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.)			
<input type="checkbox"/> [] 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/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> [] This application is the first PMA submitted by a qualified small business, including any affiliates		<input type="checkbox"/> [] The sole purpose of the application is to support conditions of use for a pediatric population	
<input type="checkbox"/> [] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> [] 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).)			
<input type="checkbox"/> [] YES <input checked="" type="checkbox"/> [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) 25-Jan-2011			

Form FDA 3601 (01/2007)

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Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105
Phone: 336 744-0157
Customer Service: 800 457-4500
Fax: 336 744-1147 • 800 743-1147
www.cookendoscopy.com

May 26, 2011

FDA CDRH DMC

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

MAY 31 2011

Received

RE: Premarket Notification for a Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

Dear Sir or Madam,

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, that Wilson-Cook Medical Inc. /Cook Endoscopy intends to manufacture and market the Cook GI Endoscopic Injection Gel Kit. The Cook GI Endoscopic Injection Gel Kit *is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.*

The following information is submitted pertaining to the Cook GI Endoscopic Injection Gel Kit:

1. **Classification Name/Code:** Endoscopic Injection Needle, Gastroenterology-Urology, FBK.
2. **Classification:** FDA has classified Similar devices as Class II, 21 CFR§ 876.1500. This device falls within the purview of the Gastroenterology and Urology Device Panel within the Division of Reproductive, Abdominal and Radiological Devices.
3. **Trade Name/Proprietary Name:** Cook GI Endoscopic Injection Gel Kit, Gel-S, Gel-N, Gel-H, GEL-K
4. **Common/Usual Name:** Endoscopic Injection Needle and Accessories
5. **Establishment Registration Number:** 1037905
6. **Performance Standards:** No performance standards have been established under Section 514 of the Federal Food, Drug and Cosmetic Act applicable to Endoscopic Injection Needles and their Accessories.
7. **Special Controls:** No Special Controls per Section 513(b) of the Federal Food, Drug and Cosmetic Act are applicable to Endoscopic Injection Needles and their Accessories.
8. An example package label and the suggested Instructions for Use for the Cook GI Endoscopic Injection Gel Kit are included in **Attachment A.**

K110

9. This device is similar with respect to Intended Use and Technological characteristics to the following predicate devices:

- *United States Endoscopy Group Dual Lumen Injector Needle Snare*, k040961, SE Decision Date 07/08/2004, manufactured by United States Endoscopy Group.
- *Cook ECHOTIP ULTRA ULTRASOUND NEEDLE*, k083330, SE Decision Date 02/06/2009, manufactured by Wilson-Cook Medical, Inc. /Cook Endoscopy

Complete device comparisons can be found in **Table 1, Section D**.

10. The Cook GI Endoscopic Injection Gel Kit Indications for Use Statement is included as **Attachment E**.

11. Refer to Sections **1-8** for a complete description of the Cook GI Endoscopic Injection Gel Kit.

12. The 510(k) Summary is included as **Attachment F**.

13. The Truthful and Accurate Statement as required by 21 CFR § 807.87 (k) is included in **Section 9**.

14. The Draft Labels and Instructions for Use can be found as **Attachments A and B** respectively.

Cook considers its intent to market this product as confidential, commercial information and we request that it be considered as such by FDA. Information contained herein should not be made available through the Freedom of Information Act, except as required by law.

Should there be any questions pertaining to this submission, please do not hesitate to contact me.

Sincerely,



Marge Walls-Walker
Senior Regulatory Affairs Specialist: Engineering
Wilson-Cook Medical, Inc. /Cook Endoscopy
[336] 744-0157 x-6290
[336] 201-5024 FAX
marge.walls-walker@cookmedical.com

510(k) Screening Checklist: Cook GI Endoscopic Injection Gel Kit

Title	Present	Inadequate	N/A
MDUFMA Cover Sheet	√		
CDRH Premarket Review Submission Cover Sheet	no		
510(k) Cover Letter	√		
Indications for Use Statement	√: Att E		
510(k) Summary or 510(k) Statement	√: Att F		
Truthful and Accuracy Statement	√: Sec 9, p. 25		
Class III Summary and Certification			√
Financial Certification or Disclosure Statement			√
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)			√
Executive Summary	√: p. i		
Device Description	√: Sec 2 p. 1		
Substantial Equivalence Discussion	√: Sec 4 p. 7		
Proposed Labeling	√: Atts. A, B		
Sterilization/Shelf Life	√: Sec 6 p. 16		
Biocompatibility	√: Sec 5, p. 12		
Software			√
Electromagnetic Compatibility/Electrical Safety			√
Performance Testing – Bench	√: Sec 7, p. 19		
Performance Testing – Animal	√: Sec 7, p. 17		
Performance Testing – Clinical			√
FORM FDA 3654, Standards Data Report for 510(k)s ²⁵			√
Kit Certification	√		√

Traditional 510(k): Cook Endoscopy GI ESD Gel Kit**Executive Summary**

The Cook Gastroenterological Endoscopic Submucosal Dissection (ESD) Gel Kit is indicated for *submucosal lift of polyps or other gastrointestinal lesions prior to excision with a snare or endoscopic device*. Predicate Devices for the Cook ESD gel kit are the *US Endoscopy Injector Snare (k040961)* and the *Cook ECHO Ultra Ultrasound Endoscopic Needle (k083330)*. Both predicate devices are intended, in part, for endoscopic mucosal/submucosal injection. The US Endoscopy Device contains a second lumen and electrical connector to facilitate the use of a snare for the excision of a bleb raised by injection of saline or other substances into the mucosa via a 25 gauge needle (23 and 25 gauge in EU). The predicate Cook device allows for the introduction of injectable substances through its 19, 23 or 25 gauge needles during endoscopic ultrasound. The subject device is not intended for use with an ultrasound needle, but is intended to inject its accessory, sodium carboxymethylcellulose, through a 19 gauge needle into the submucosa. **Table 1** shows the comparison between the subject device and its predicates:

Table 1: Predicate Device Comparison:

Parameter	Cook Endoscopy Endoscopic Submucosal Dissection Gel (subject device)	US Endoscopy Injector Needle Snare (k040961)	Cook Endoscopic ECHO Ultra Ultrasound Needle (k083330)
Intended Use	This device is indicated for sub mucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device	The dual lumen Injector Needle Snare is indicated for use with an Olympus Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through a flexible endoscope, prior to electrical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.	This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract
Supplied Sterile	Yes (EO-needle, Steam-gel)	Yes (EO)	Yes (EO)
Duration of Use	Disposable, Single Use	Disposable, Single Use	Disposable, Single Use
Needle Gauge	19 ga	25 ga	19, 22, 25 ga
Needle material	302/304 Stainless Steel	302/304 Stainless Steel	302/304 Stainless Steel

Traditional 510(k): Cook Endoscopy GI ESD Gel Kit

Parameter	Cook Endoscopy Endoscopic Submucosal Dissection Gel (subject device)	US Endoscopy Injector Needle Snare (k040961)	Cook Endoscopic Ultrasound HD Needle (k083330)
Needle length (extended)	1 cm: non-adjustable	0.5 cm: non-adjustable	0-8 cm (adjustable)
Catheter (sheath) material	Blue PEEK	Polymer	Blue PEEK
Catheter (sheath) length	220.3 cm +/- 3 mm	230 cm	142.2 cm +/-2mm
Catheter (sheath) diameter	.068" (1.73 mm) (5Fr)	9 Fr (3 mm)	5 Fr (1.73 mm)
Endoscope compatibility (channel)	2.8 mm accessory channel/ non-ultrasound	3.7 mm accessory channel/non-ultrasound	2.0 mm accessory channel/ultrasound
Handle locking mechanism	Luer-type	Luer-type	Luer-type
Syringe	Yes, pre-filled with injectable	No	Yes, unfilled, for aspiration only
Snare or Excision Device	No	Yes	No

The predicted clinical outcomes of the Cook Endoscopic ESD gel kit are significant. Similar to the predicate injector/snare, the ESD gel kit lifts submucosa and mucosa away from the muscularis during tissue resection procedures such as Endoscopic Mucosal Resection (EMR) or Endoscopic Submucosal Dissection (ESD) in an effort to prevent perforation or dissection of the muscularis layer of the GI tract.

In current, common clinical practice, EMR techniques are limited by their inability to achieve *en bloc* resection of lesions for complete histopathologic evaluation. EMR is typically used for removal of lesions smaller than 2 cm or for piecemeal removal of larger lesions. A major concern with EMR is the uncertainty as to whether the lesion and its margins have been completely removed. This is very important for cases of early malignant lesions since residual tumor increases the rate of local tumor recurrence

Endoscopic submucosal dissection (ESD) is a minimally invasive endoscopic technique that was developed to overcome the limitations of conventional EMR. The goal of *en bloc* resection is to remove the entire lesion in one piece, including tumor margins, as compared to piecemeal resection seen in EMR. ESD allows for the *en bloc* removal of large, flat GI tract lesions confined to the mucosal or submucosal layers. The technique involves submucosal injection of a solution to lift the lesion away

Traditional 510(k): Cook Endoscopy GI ESD Gel Kit

from the muscularis followed by dissection of the lesion using various endoscopic devices (snares, needle knives etc.).

The Cook GI ESD Gel Kit is comprised of three main components, a sterile injection needle attached via Luer lock to a pressure gauge, a filled, sterile injection syringe and a non-sterile handle. The needle and gauge are sterilized using Ethylene Oxide (EO), the filled syringe is steam sterilized. The syringe is filled with lightly tinted (b) sodium carboxymethylcellulose.

As indicated in the predicate device labeling and promotional materials, several non-viscous, watery solutions are recommended to lift tissue; the viscosity of these solutions is compatible with 25 gauge needles; however the resorption or dissipation of these lifting agents is rapid, particularly after initiation of the resection procedure. One of the limitations to date for successful ESD procedures has been the unavailability of an injection solution that could lift the mucosa to be resected and maintain the bleb for the duration of the procedure without absorption or dissipation. The ESD gel is (b) sodium carboxymethylcellulose (CMC), a compound long recognized as a device to adhere and cushion dentures, medialization of paralyzed vocal folds to improve voice quality and/or airway protection and as a short-term ureteral blocking agent during lithotripsy procedures. In the ESD procedure this viscous gel lifts the bleb, which remains intact during the procedure and sloughs through the GI tract upon completion of the resection. Prior to introduction of the CMC, a small starter bleb is raised with saline as a precautionary measure to prevent injection of the gel into the muscularis. The gauge component at the proximal end of the device is a safety mechanism, visible to the physician or nurse to indicate cessation of CMC flow due to catheter kink or needle bend. Pre-clinical testing and engineering analyses have shown that 1500 psi is the maximum safe pressure for the system. Pressures beyond that will compromise the safety and or effectiveness of the procedure, due to excess leakage of the gel at unintended locations or detachment of components under pressure.

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Attachments

- Attachment A Draft Labels for Cook GI Endoscopic Injection Needle Gel Kit
- Attachment B Draft IFU for Cook GI Endoscopic Injection Needle Kit
- Attachment C Predicate Device (US Endoscopy) IFU
- Attachment D Predicate Device (US Endoscopy) Promotional Material
- Attachment E Indications for Use Statement
- Attachment F 510(k) Summary
- Attachment G Engineering Drawings
- Attachment H Biological Risk Assessment
- Attachment I Biocompatibility Test Reports
- Attachment J Clinical Literature Summary

1.0 Intended Use:

The Cook GI Endoscopic Injection Gel Kit is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

2.0 Device Description:

The Cook GI Endoscopic Injection Gel Kit (GEL-K) contains three components, packaged separately, but assembled at the time of the procedure into one unit. The three components are:

- The handle with threaded plunger (GEL-H)
- The syringe filled with (b) sodium carboxymethylcellulose (CMC) dissolved in sterile water with blue tint (GEL-S)
- The endoscopic injection needle with pressure gauge (GEL-N)

A photo of the assembled device can be seen in **Figure 1** below. Each component is then individually discussed. Engineering drawings for major components and complete assembly can be found in **Attachment G**.

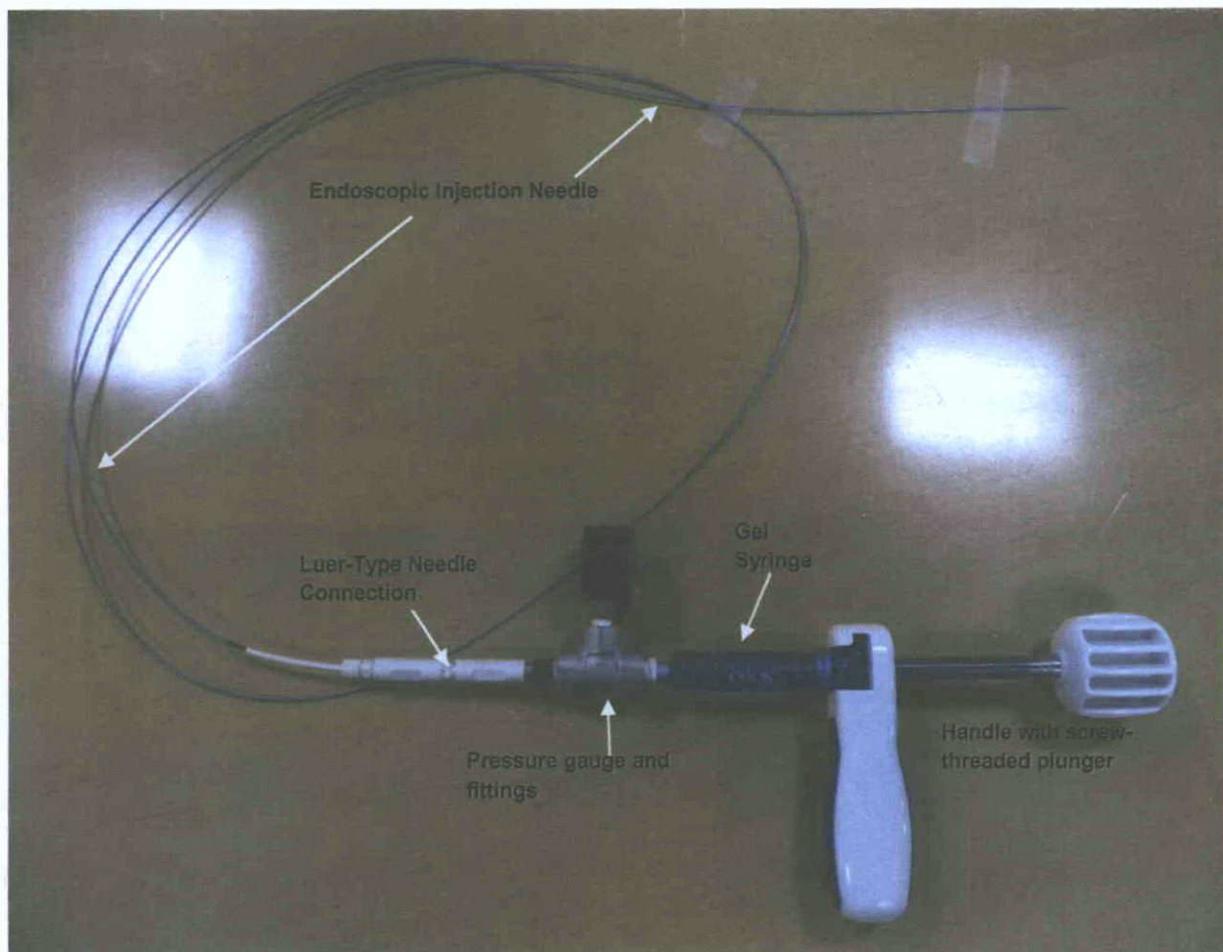


Figure 1: Cook GI Endoscopic Injection Gel Kit

Endoscopic Injection Needle:

The Endoscopic Injection Needle is identical to the 19 gauge Cook ECHO Ultrasound Injection Needle (k083330, clearance date 2.6.2009) with respect to materials of construction of the stainless steel needle and blue PEEK sheath. The difference in length of the sheath (~220cm for subject device vs. ~142 cm for ECHO device) is due to the termination of the sheath at the base of the ultrasound handle as opposed to the sheath running the entire length of the subject needle. The needle lengths are identical with ~75 cm of the ECHO needle passing through the handle of that device. Additionally, the ECHO needle has a range of extension from the distal end of the sheath of 0-8 cm, controlled by the handle, whereas the Gel needle extends only 1 cm out of its sheath. This is attributed to the different indications and clinical techniques associated with the respective needles.

The proximal end of the needle as illustrated in **Figure 1** and detailed in **Figure 2** terminates into a male/female Luer-type connection that control extension and retraction of the distal end of the needle.



Figure 2: Detail of Luer-type connection at proximal end of needle

This connection is then adapted into and through the pipe fitting using nylon and Delrin[®] connectors as shown in **Figure 3**. These connectors terminate in a female Luer-type adaptor that will accept connection to the male Luer-type syringe.



Figure 3: Needle to syringe connectors/adaptors showing opening for stem-mount gauge

Perpendicular to the proximal end of the needle is the 3000 psi, 21 MPa (Max) stem-mount pressure gauge shown in **Figures 4 and 5**. This pressure gauge is integrated into the gel system so the physician can observe system pressure during the procedure. Because of the bends, curves and occasional torturous anatomy of the GI tract as well as the articulation function of endoscopes, it is not unusual for an endoscopic accessory to become pinched (in an endoscope elevator) or bent during endoscope articulation or retroflexion. During Use the GI Endoscopic Injection Gel system, builds pressure (force/area) by pushing a viscous material through a narrow tube (needle) over the 220 cm length, the IFU instructs that the maximum pressure during use not exceed 1500 psi, which would indicate a bent or compromised needle. At this and greater pressures, leakage of the gel outside the system and cracking or disconnection of components may occur.

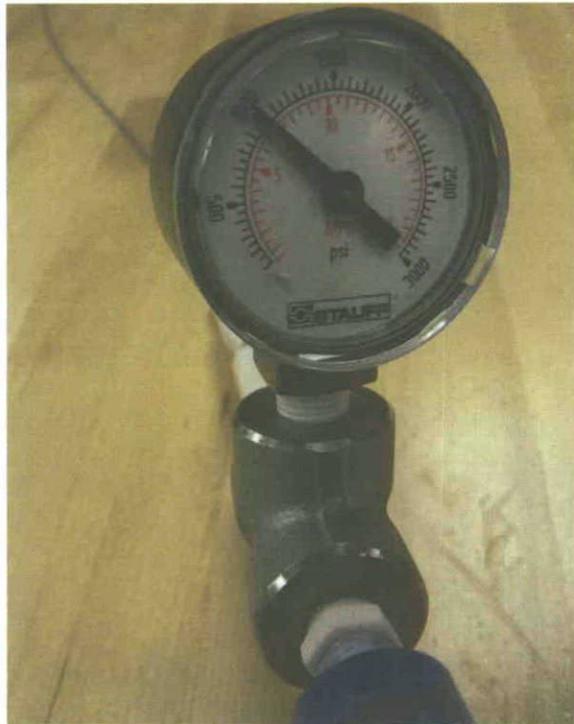


Figure 4: Photo of pressure gauge indicating system under pressure

The accuracy of the gauge is as follows as defined by the gauge vendor:

- 3% for 0-25% of scale
- 2% for 25%-75% of scale
- 3% for 75%-100% of scale

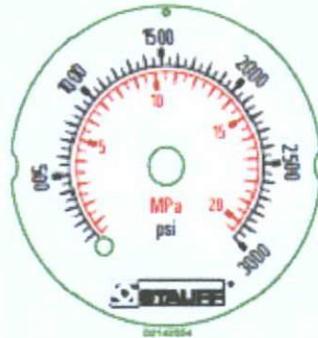


Figure 5: Schematic of Gauge Face showing dual scale (PSI / PASCAL) and peak pressure

Per the IFU, peak recommended pressure is 1500 psi, average pressure during injection is ~1000 psi. Normal operating pressures are less than 50% of the gauge range yielding a usable accuracy of 2% of scale.

ESD Gel Syringe:

The blue syringe containing the GI Endoscopic Injection Gel is identical in materials of composition, manufacturing methods and vendor as the syringe component in the Cook Incorporated *Vertefix*[™] Vertebroplasty Bone Cement kit cleared to market via k042691 (clearance date 11.08.2005). The primary difference in the two syringes is that the Vertebroplasty syringe is distributed unfilled but accompanied by bone cement mix components and the syringe in the subject device comes pre-filled with a CMC solution capped at both ends, then steam sterilized. Caps are later removed for connection in the system. See **Figure 1** for placement of the syringe in the system. See **Figure 6** for a line drawing of the of the unfilled syringe. See **Figure 7** for a photo of the filled and capped syringe.

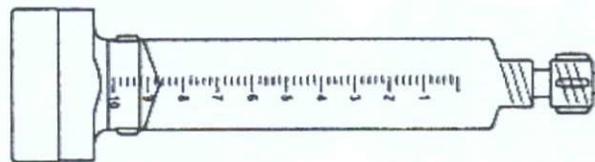


Figure 6: Drawing of unfilled syringe

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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit



Figure 7: Photo of filled, capped syringe

The syringe is filled with a pre-mixed solution of 3% weight to volume CMC, sterile water and .001 .003g/175 mL (0.0006-0.0017%) indigo carmine FD&C blue tint. The tint allows easier endoscopic visualization during the dissection procedure. Sodium Carboxymethylcellulose (CMC) is a compound long recognized as a device to adhere and cushion dentures; it is a Class 1 device per 21 CFR 872.3410 when used alone or with ethylene oxide homopolymer and 21 CFR 872.3490 when used alone or in conjunction with polyvinylmethylether maleic acid calcium sodium double salt. Mixtures including CMC are Class II devices per 21 CFR 874.3620 when used as as an injectable laryngeal augmentation agent for medialization of paralyzed vocal folds to improve voice quality and/or airway protection. Sodium CMC is a frequent element of mixtures classified under 21 CFR 876.4680 as Dissolvable Gels for Preventing ureteral Stone Migration during lithotripsy; once the fragmentation of stones is complete, the gel is endoscopically irrigated, dissolves and is passed out of the body via the ureter.

A complete Risk Assessment of the Biological Safety of Sodium CMC and indigo carmine can be found in **Appendix H**. Biocompatibility Tests on the specific gel in the subject device post-sterilization using moist heat can be found in **Appendix I**.

The Handle

The threaded handle at the proximal end of the device is identical in materials of composition, manufacturing methods and vendor as the syringe component in the Cook Incorporated *Vertefix™* Vertebroplasty Bone Cement Kit cleared to market via k042691 (clearance date 11.08.2005). Once uncapped the filled syringe is fitted into the handle adjacent to the syringe plunger. The syringe is then twisted 90° to lock into the handle and allow fixed contact between the plunger in the syringe and the threaded handle mechanism. Arrows on the handle piece indicate which direction to turn the handle to begin the flow of gel through the system. Reversing the direction of the handle stops forward movement of gel. See **Figure 8** for a drawing of the handle only. See **Figure 1** for placement of the handle in the system.



Figure 8: Handle Drawing

3.0 Clinical Background

Historically, pre and early stage malignant lesions of the digestive tract have been removed using highly invasive techniques such as surgical resection. In addition to the serious and inherent risks, longer hospitalization and healing times are associated with the surgical procedure. Lymph node metastasis of early gastric cancer is relatively infrequent and less invasive methods for removal of early gastric cancer lesions are being utilized more frequently. Compared to surgery, endoscopic techniques, including EMR and ESD are less invasive and result in faster postoperative recovery and shorter hospital duration. With the ability to obtain specimens for histological analysis, endoscopic techniques aid in the diagnosis of lesions localized to the mucosa or submucosa with improving accuracy; allowing select and appropriate treatment of early gastric cancer and other gastrointestinal lesions.

Conventional endoscopic mucosal resection (EMR), often referred to as "saline-assisted" polypectomy or "strip-off biopsy," is an endoscopic technique first introduced in Japan for removal of lesions confined to the mucosal or submucosal layers of the gastrointestinal (GI) tract. The procedure involves creation of superficial cautery marks to outline the margins of the targeted lesion followed by methods to separate the lesion from the muscular layer to facilitate lesion removal. The "lift and cut" method uses a submucosal injection to lift the lesion prior to resection using an electric cutting current while the "suck and cut" method separates the lesion from the muscular layer with or without submucosal injection, depending on the device chosen for resection (i.e. electrocautery snare, grasping forceps, mucosectomy device, band ligation device). EMR is accepted worldwide as an effective therapeutic modality for the treatment of gastrointestinal lesions limited to the mucosa. However, EMR techniques are limited by their inability to achieve *en bloc* resection of lesions for complete histopathologic evaluation. *En bloc* resection is the removal of the entire lesion in one piece as compared to piecemeal resection. EMR is typically used for removal of lesions smaller than 2 cm or for piecemeal removal of larger lesions. A major concern with EMR is the uncertainty as to whether the lesion, particularly the margins have been completely removed. For cases of early malignant lesions, residual tumor/margins increase the rate of local tumor recurrence.

Endoscopic submucosal dissection (ESD) is a minimally invasive endoscopic technique that was developed to overcome the limitations of conventional EMR. ESD allows for the *en bloc* removal of large flat GI tract lesions confined to the mucosal or submucosal layers, which may lower the rate of local tumor recurrence. The technique involves submucosal injection of a solution to lift the lesion away from the *muscularis propria* followed by dissection of the lesion using various endoscopic devices.

The injection solution properties are important to the ESD technique. Normal saline has been widely used to assist with endoscopic resection; however, it is difficult to achieve and maintain adequate mucosal lift, due to the rapid absorption of saline by the surrounding tissues. This is problematic as the inability to adequately lift lesions and maintain those lifted lesions during endoscopic procedures may lead to additional injections, failed snaring, increased procedure time, perforation, and/or incomplete resection. In an effort to provide a more sustained mucosal lift, the safety and efficacy of various injection solutions has been reported in the literature. These solutions include hydroxypropyl methylcellulose, sodium carboxymethylcellulose, hyaluronic acid, hypertonic sodium chloride, glycerol, dextrose, albumin, fibrinogen, and autologous blood. The advantages and disadvantages vary for each injection solution. Dextrose and hypertonic sodium chloride are inexpensive and readily available but have been shown to

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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

cause significant local inflammation at the injection sites. Hyaluronic acid and hydroxypropyl methylcellulose create a long-lasting cushion but hyaluronic acid is expensive, not readily available, and requires special storage requirements, and hydroxypropyl methylcellulose has been shown to cause local inflammation at the injection sites. The ideal solution should be readily available, nontoxic, and easy to inject, and provide a long-lasting submucosal cushion.

Like other injection solutions, the Cook GI Endoscopic Injection Gel is intended to produce submucosal lift of gastrointestinal lesions prior to excision. Unlike some other currently available solutions, the choice of the agent for the Cook GI Endoscopic Injection Gel is intended to keep the bleb lifted for a reasonable amount of procedural time, be readily available and be non-toxic and non-inflammatory. Results from a published study using CMC as an injection solution in a porcine model reported that ESD by submucosal injection was performed without difficulty, lesions were extracted with grasping forceps, and there were no procedure-related complications, such as major bleeding or perforation. This study provides evidence that viscous CMC creates a long-lasting fluid cushion which remains intact during the procedure and sloughs through the GI tract upon completion of the resection.

Both ESD and EMR are technically demanding procedures. The procedure length is highly variable and depends on the degree of difficulty of the resection. The lesion size, anatomical location, tumor fibrosis, and patient co-morbidities may affect the degree of difficulty of the resection. Bleeding is the most common potential complication for both procedures with rates ranging from 1% to 45%. Most bleeding occurs during the procedure or within the first 24 hours; however, delayed bleeding has been reported. Bleeding has not been reported to occur any more frequently with ESD compared to EMR. Stenosis is a potential procedural complication related to removal of the lesion. It is typically limited to the esophagus and has been reported to occur in 6% to 26% of patients. A risk specific to the injection procedure includes inadvertent injection of the solution into the muscularis; however, users of the Cook GI Endoscopic Injection Gel Kit are instructed to use a conventional endoscopic injection needle and saline to raise a starter bleb prior to injection of the Gel to decrease this risk. See **Appendix B** for complete Instructions for Use for the Cook ESD Gel. See **Appendix A** for draft package labeling. See **Appendix J** for a review of current literature on ESD and EMR techniques, specifically focused on the materials chosen for injection.

Overall, endoscopic resection techniques, especially with the aid of submucosal lifting solutions can be performed safely with comparable results to open surgery but with decreased morbidity and shorter recovery time due to the minimally invasive nature of the procedures.

4.0 Substantial Equivalence Discussion

The Cook GI Endoscopic Injection Gel Kit is substantially equivalent to the predicate devices with respect to the indications for use, intended use, materials of construction and the technological characteristics. A comparison of the key features of the subject device and the predicates is included in **Table 1** below.

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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit**Table 1: Predicate Device Comparison**

Parameter	Cook GI Endoscopic Injection Gel Kit (subject device)	US Endoscopy Injector Needle Snare (k040961)	Cook Endoscopic Ultrasound HD Needle (k083330)
Intended Use	This device is indicated for sub mucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device	The dual lumen Injector Needle Snare is indicated for use with an Olympus Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through a flexible endoscope, prior to electrical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes.	This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract
Supplied Sterile	Yes (EO-needle, Steam-gel, Handle is non-sterile)	Yes (EO)	Yes (EO)
Duration of Use	Disposable, Single Use	Disposable, Single Use	Disposable, Single Use
Needle Gauge	19 ga	25 ga	19, 22, 25 ga
Needle material	302/304 Stainless Steel	302/304 Stainless Steel	302/304 Stainless Steel
Needle length (extended)	1 cm: non-adjustable	0.5 cm: non-adjustable	0-8 cm (adjustable)
Catheter (sheath) material	Blue PEEK	Polymer	Blue PEEK

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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit**TABLE 1: Predicate Device Comparison (con't)**

Parameter	Cook Endoscopy Endoscopic Submucosal Dissection Gel (subject device)	US Endoscopy Injector Needle Snare (k040961)	Cook Endoscopic Ultrasound HD Needle (k083330)
Catheter (sheath) length	220.3 cm +/- 3 mm	230 cm	142.2 cm +/-2mm
Catheter (sheath) diameter	5 Fr (1.73 mm)	9 Fr (3 mm)	5 Fr (1.73 mm)
Endoscope compatibility (channel)	2.8 mm accessory channel/ non-ultrasound	3.7 mm accessory channel/non-ultrasound	2.0 mm accessory channel/ultrasound
Handle locking mechanism	Luer-type	Luer-type	Luer-type
Syringe	Yes, pre-filled with injectable	No	Yes, unfilled for aspiration only

The 510(k) Substantial Equivalence Decision Making Process as outlined in ODE Guidance No. K 86-3, *Guidance on the CDRH Premarket Notification Review Program*, was applied to evaluate substantial equivalence. Responses to the questions posited by the Guidance lead to the determination that the Cook GI Endoscopic Injection Gel Kit is substantially equivalent to the US Endoscopy Injector Needle Snare with respect to Intended Use and technological characteristics, The Cook GI Injection Gel Kit shares significant technological characteristics with the Cook ECHO Ultrasound needle although not intended for use with an ultrasound endoscope.

1. Does the new device have the same intended use?

Yes. The primary Intended Use of the subject device and the predicate Injector Snare is *for endoscopic injection of media for submucosal lift of polyps or other mucosal lesions using direct visualization, through a flexible endoscope, prior to electrical excision*. The Cook GI Injection Gel Kit is not intended for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding or tattooing of sites for future surgical procedures. The ESD Kit shares a component of the Intended Use with the Cook ECHO needle for *delivery of injectable materials within the GI tract*.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc?

Yes.

- All needles are constructed of 302/304 Stainless Steel
- All needles are intended for injection within the GI tract
- All needles are of lengths appropriate to their intended clinical application
- All needles are intended to be used with an endoscope; the use of an ultrasound endoscope with the ECHO is noted.
- All needles are of similar length and encased in a polymer sheath during construction, the sheath material on the subject device and ECHO needle are identical.
- All needles are ethylene oxide sterilized.
- All needles are intended for single use only.

The primary Technological Characteristics of the Cook GI Endoscopic Injection Gel Kit that differs from the predicates is the inclusion of a 10 cc syringe filled with sodium carboxymethylcellulose (CMC) and placement of a pressure gauge between the injection needle and the syringe. After identification of a mucosal lesion suitable for dissection, a starter bleb is created using a conventional GI injection needle and saline. Once the bleb is formed the needle of the ESD kit is introduced into the bleb to transport the CMC to the selected submucosal area. Delivery of the viscous gel across a ~ 200 cm length through a 19 ga. needle is expected to create pressure (force over area); the gauge is in place to monitor the pressure to prevent excessive gel leakage or component cracking/disconnection. Dissection/Excision of the raised lesion can be with any of the currently available endoscopy accessories indicated for that purpose (endoscopic snares, knives etc.)

A second Technological Characteristic related to the gel, but different from the predicates is the use of Moist Heat Sterilization for the gel and syringe. The Moist Heat sterilization cycle was validated according to ISO 17665 with a validated SAL 10^{-6} . All Verification and Validation activities used sterile devices to assure that sterilization did not affect the viscosity of the gel or operational capabilities of the assembled device.

3. Could the new characteristics affect safety or effectiveness?

Yes, the new characteristics could affect safety and effectiveness.

4. Do the new characteristics raise new types of safety and effectiveness questions?

No, the new characteristics do not raise new types of safety and effectiveness questions. In particular:

- a. Use of CMC as volume filler: As mentioned in Section 3, Clinical Background, of this submission, sodium carboxymethylcellulose (CMC) is a well known medical device when used alone or as a carrier for use in other medical specialties such as urology, dentistry and ENT. Notwithstanding its well known applications, Cook performed both a Risk Assessment

to further examine the toxicological background of CMC and FD&C Blue #2 as well as biological testing per G-95 and ISO 10993-1 to mitigate any toxicological risk of the specific mixture of Cook's sterile ESD gel.

- b. **Moist Heat (Steam) Sterilization of the gel and syringe:** Moist Heat (steam) sterilization is a recognized and effective method for sterilization of medical devices. Specifically several currently approved/cleared and commercialized devices solely composed of or containing CMC are also sterilized via steam cycles including "*Coaptite*" [P040047] and "*Juliess*" [k060815], both intended for use in thoroplasty, and "*CalMatrix*" [k0413211] bone graft. Unlike these comparable devices, the Cook GI Endoscopic Injection Gel is not implanted or absorbed into the muscularis and sloughs through the GI tract and out of the body once the affected tissue is removed. Details on the Steam Sterilization Validation can be found in Section 6 of this submission.

5. Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The ISO 10993 Series of Standards and the FDA Blue Book Memorandum G-95 present recommendations for evaluating the toxicological risk of materials and EO sterilization used in medical devices. Additionally, ISO 17665-1 and the TIR (-2) provide guidance on the validation of Moist Heat Sterilization Cycles and their validation.

6. Are performance data available to assess the effects of the new characteristics?

Yes. See Section 5 and **Appendices H and I** for a plan and summary of the biocompatibility testing performed. No testing was performed on the needle and sheath as they are identical to the cited ECHO predicate. Testing was performed on the syringe, despite being identical to the syringe used in *Vertefix*™ Vertebroplasty Bone Cement kit cleared to market via k042691 (clearance date 11.08.2005) due to the change in sterilization method from ethylene oxide to moist heat.

7. Do performance data demonstrate equivalence?

Yes. Pre-clinical testing provides support for the performance goals of the Cook GI Endoscopic Injection Gel Kit. A summary of all testing for this device can be found in Section 7. Additionally, significant pre-clinical and clinical data is available in the literature on multiple lifting agents for use in Endoscopic Resection/Dissection. See Appendix J for a clinical literature review of the agents and techniques.

In summary the Cook GI Endoscopic Injection Gel Kit is substantially equivalent to the named predicates in terms of Intended Use, Indications for Use, Technological Characteristics and Materials. The Technological Characteristics that differ between the subject device and the predicates are the

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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

provision of a pre-filled, sterile syringe of sodium Carboxymethylcellulose for injection below the mucosa to act as a lifting agent for sessile polyps or mucosal lesions in the GI tract prior to excision /dissection. This material is well known and well characterized in varying concentrations as a medical device across medical disciplines.

Based on the responses to the above questions posited in FDA Guidance No. K 86-3 and the data presented in *Sections 5, 6 and 7* the Cook GI Endoscopic Injection Gel kit is substantially equivalent to the currently marketed predicate US Endoscopy Dual lumen Injector Snares and Cook ECHO Ultrasound Needle.

5.0 Materials of Construction and Biocompatibility:

(b) (4)



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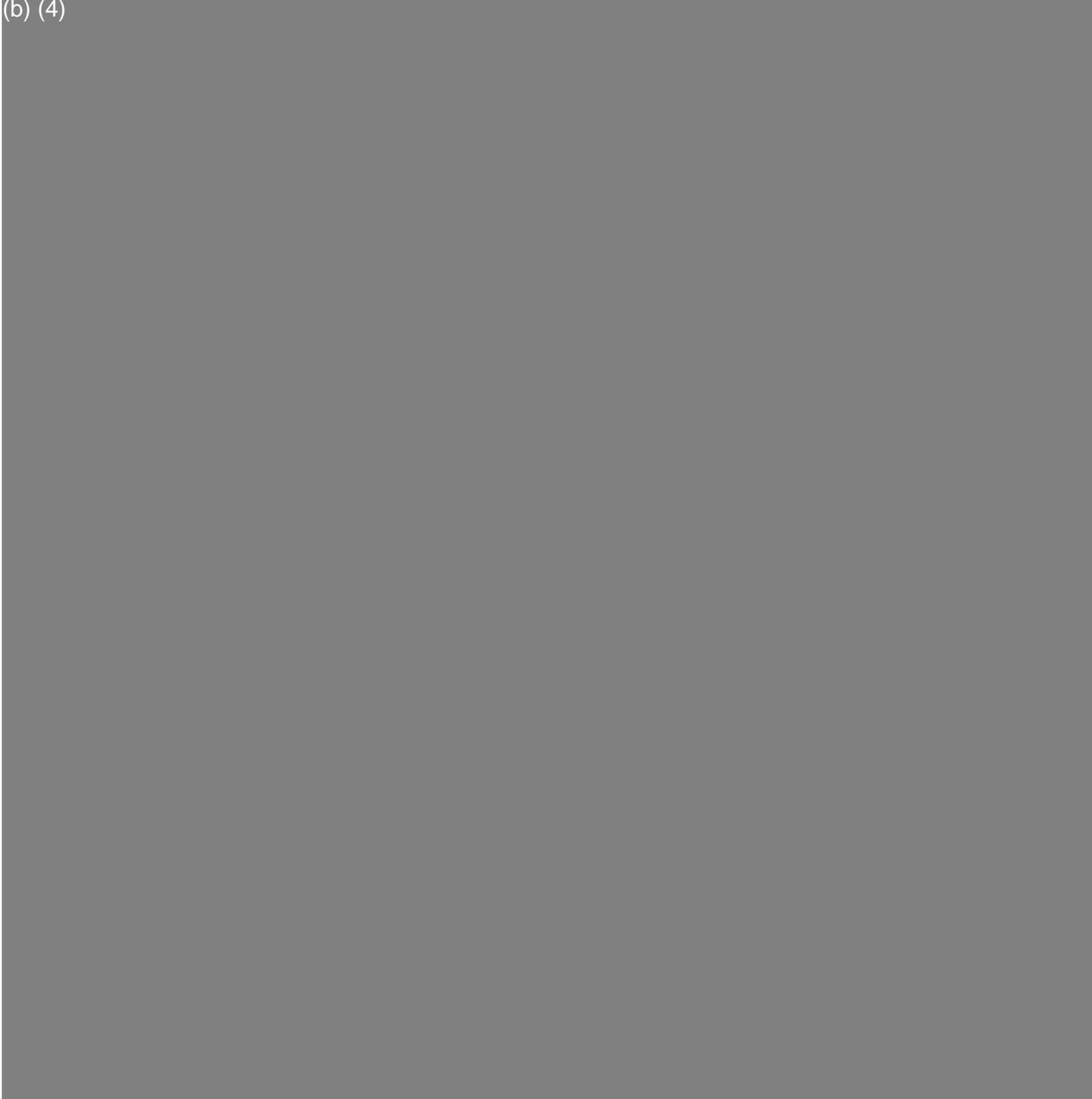
Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)

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Table 3: GI Endoscopic Injection Gel Kit-Needle

(b) (4)

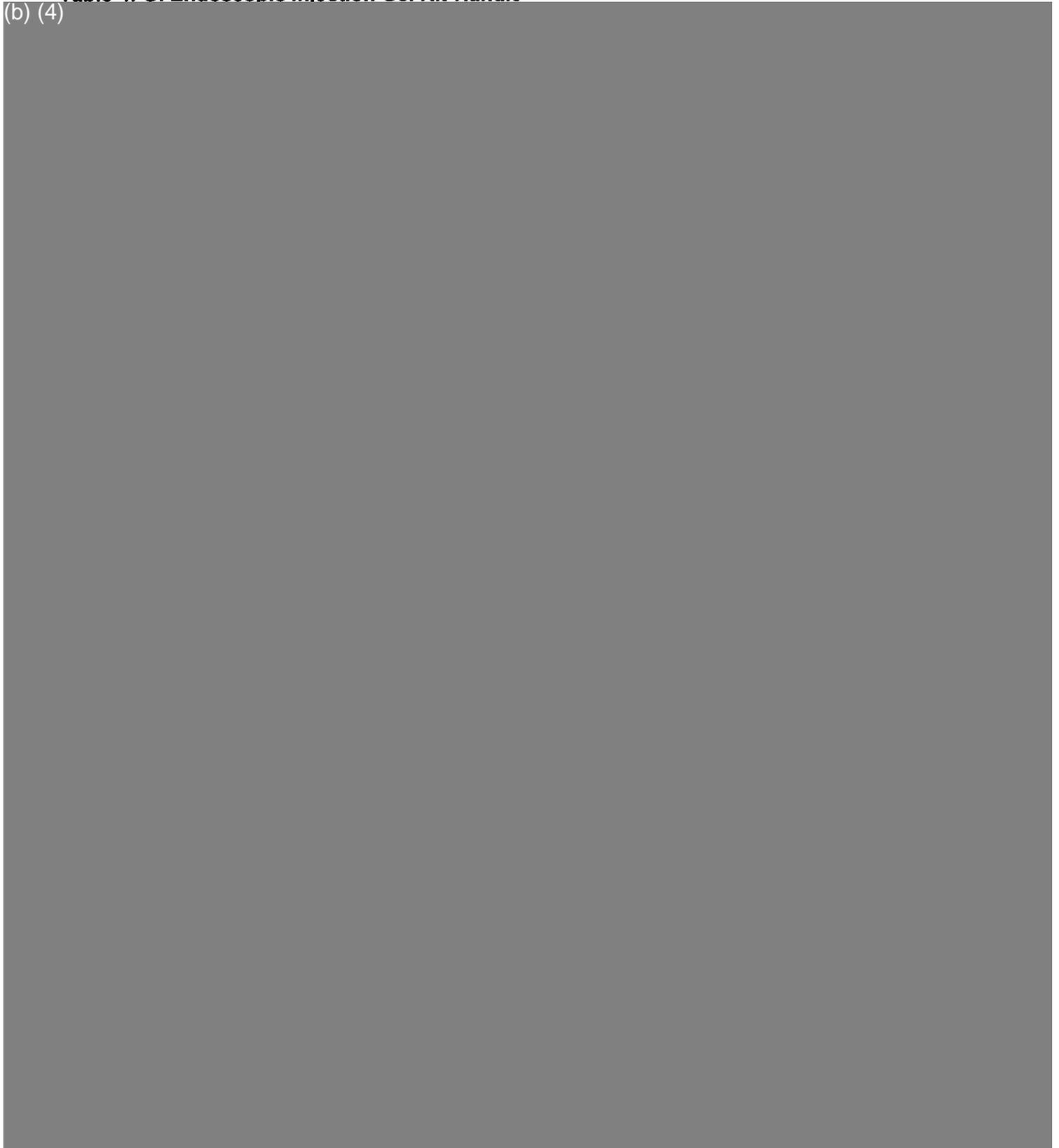
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Table 4: GI Endoscopic Injection Gel Kit-Handle

(b) (4)



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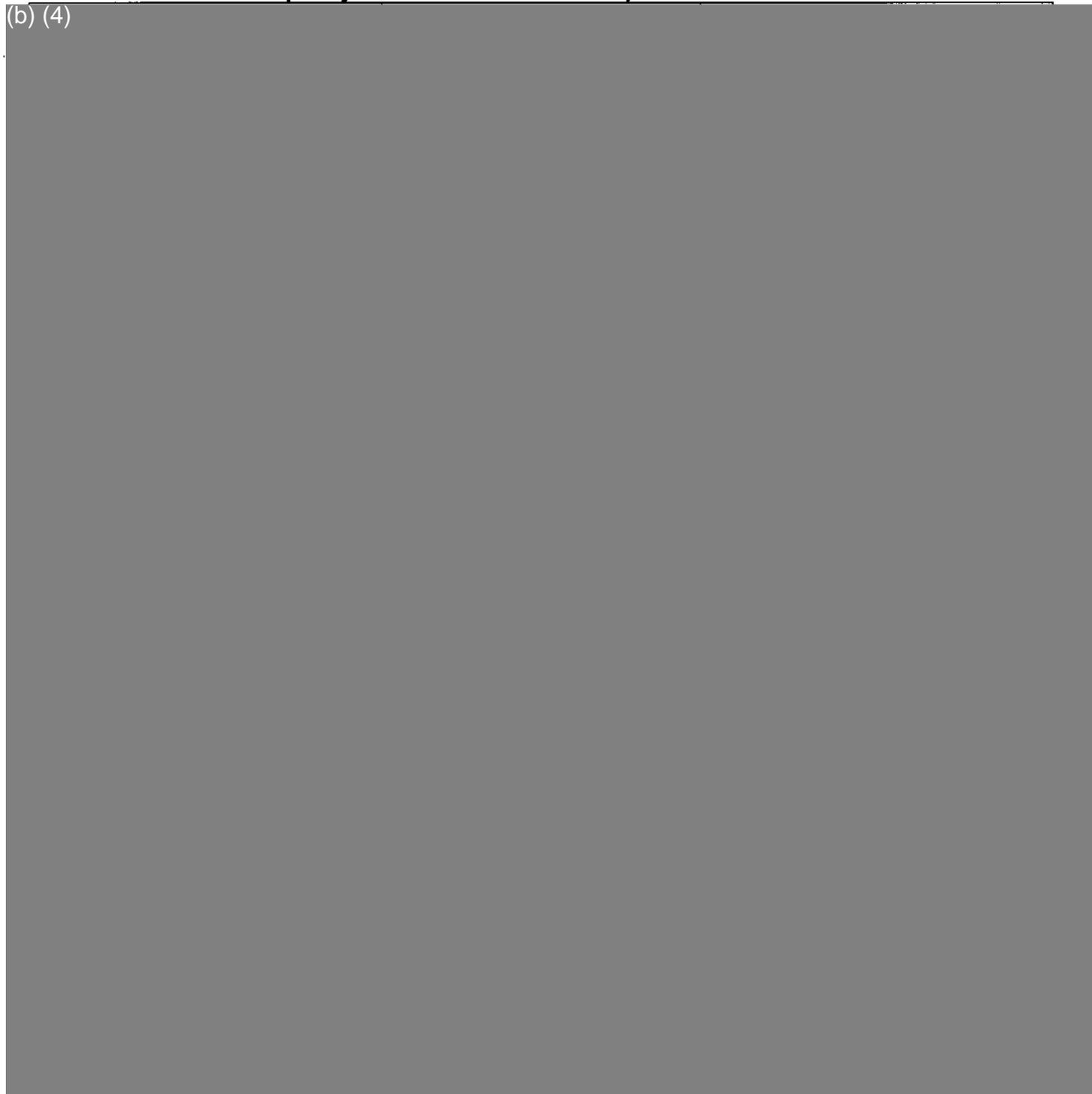
Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

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Table 5: GI Endoscopic Injection Gel Introducer Components

(b) (4)

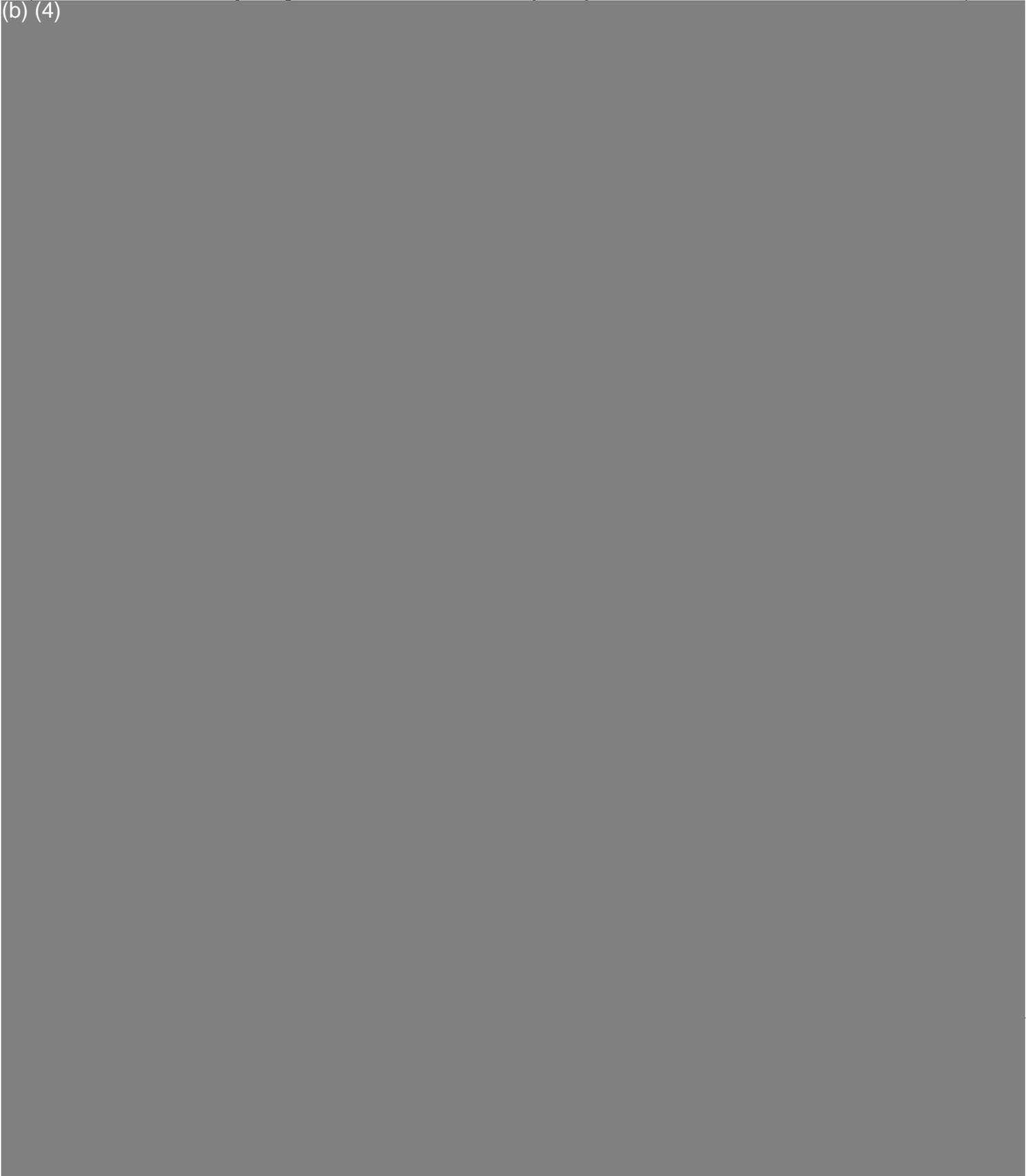
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Table 6: GI Endoscopic Injection Gel with FD&C #2 (con't)

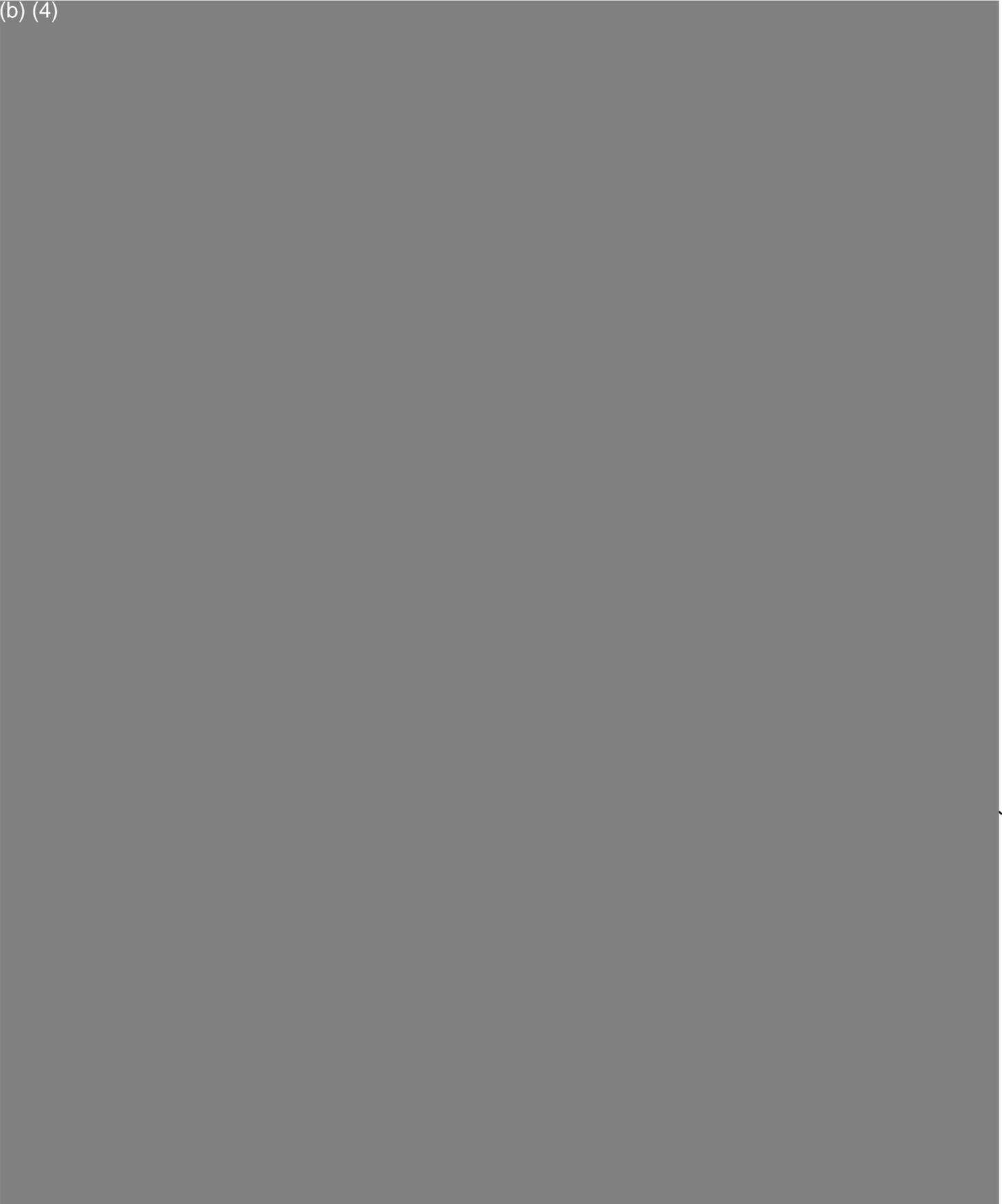
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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)

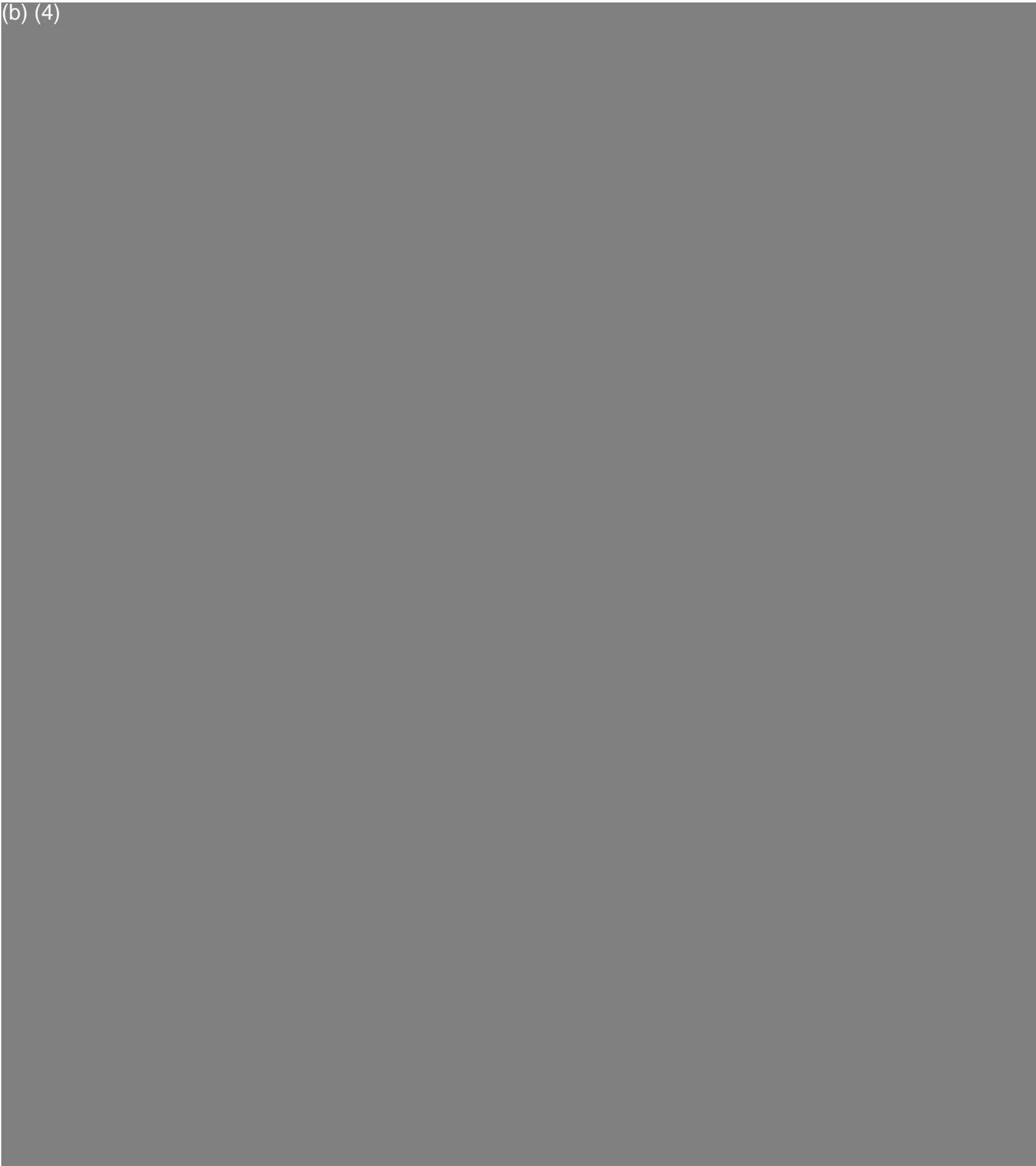


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7.1: Animal Testing

(b) (4)



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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)



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Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)



May 26, 2011

Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

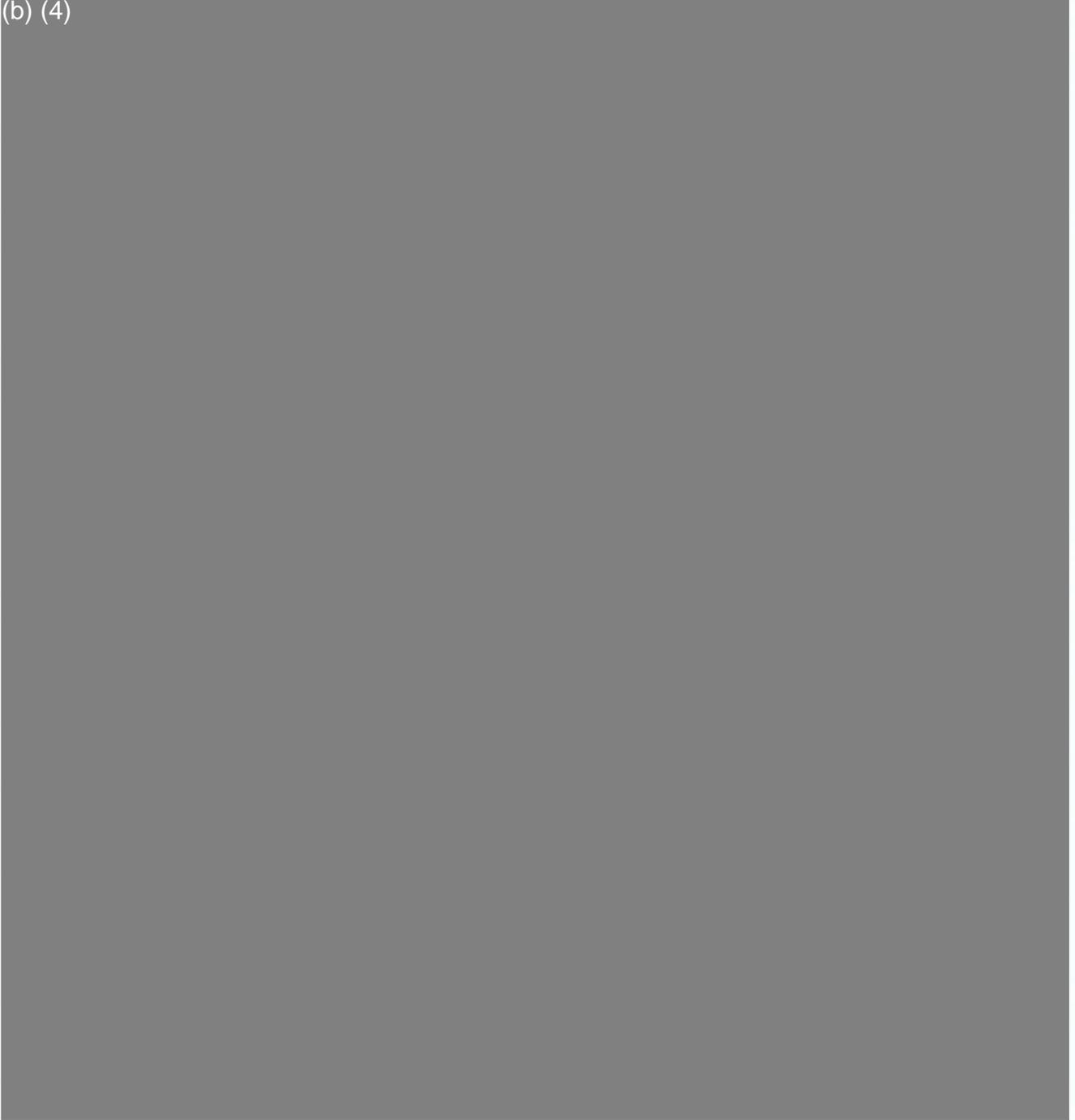
(b) (4)



May 26, 2011

Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

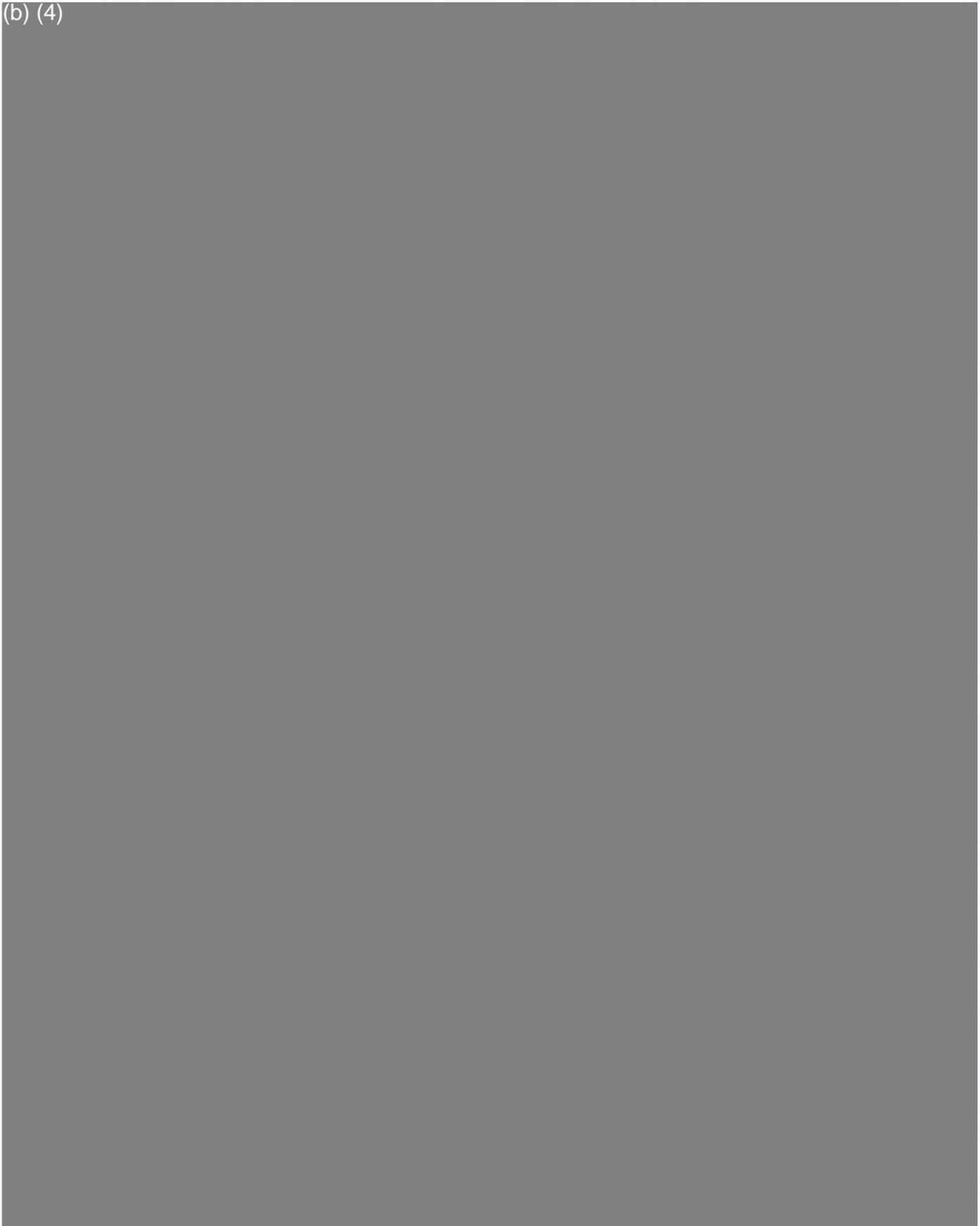
(b) (4)



May 26, 2011

Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)



May 26, 2011

Traditional 510(k): Cook GI Endoscopic Injection Gel Kit

(b) (4)



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Section 9: **Truthful and Accurate Statement**

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as a senior Regulatory Affairs Specialist of Wilson-Cook Medical, Inc. /Cook Endoscopy, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Marge Walls-Walker

(Typed Name)

5.26.2011

(Date)

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

GEL-K

GI ENDOSCOPIC INJECTION GEL KIT

KIT INCLUDES:

1 GEL NEEDLE

1 GEL SYRINGE

1 GEL HANDLE

SINGLE USE, DISPOSABLE

Rx ONLY

GEL-H

GI ENDOSCOPIC INJECTION GEL HANDLE

SINGLE USE, DISPOSABLE

Rx ONLY

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GEL-N

GI ENDOSCOPIC INJECTION GEL NEEDLE
SINGLE USE, DISPOSABLE
Rx ONLY
STERILE

COMPATIBLE WITH 2.8mm
ACCESSORY CHANNEL

GEL-S

GI ENDOSCOPIC INJECTION GEL SYRINGE
SINGLE USE, DISPOSABLE
Rx ONLY
STERILE

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CONFIDENTIAL

DRAFT

Gel Kit

INTENDED USE

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

NOTES

This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

This device is supplied with sterile and non-sterile components.

Do not use this device for any purpose other than stated intended use.

If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.

Store in a dry location, away from temperature extremes.

Use of this device restricted to a trained healthcare professional.

CONTRAINDICATIONS

Those specific to primary endoscopic procedure to be performed in gaining access to desired target site. Device not to be used in vascular system.

POTENTIAL COMPLICATIONS

May include, but not limited to: muscularis perforation and minor acute bleeding.

PRECAUTIONS

Refer to package label for minimum channel size required for this device.

The syringe is for use with the handle and needle only.

This device must be used with direct endoscopic visualization.

WARNINGS

The safe and effective use of this high-pressured device is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained endoscopy staff. It is important that instructions supplied with this device be read, understood and followed before use.

Device should not be used as a bulking agent.

Do not exceed recommended working pressure of 1500 psi.

KIT COMPONENTS

- Needle
- Syringe
- Handle

EQUIPMENT NEEDED

- Saline-filled syringe
- Standard endoscopic injection needle

SYSTEM PREPARATION

1. Remove needle from package and uncoil catheter.
2. Remove syringe from package.
3. Remove clear caps from proximal and distal end of syringe. **Note:** Use pliers if necessary.
4. Attach distal end of syringe to white adapter on proximal end of gauge of needle so that syringe cap is vertically aligned with gauge.
5. Attach proximal end of syringe to handle with knob closest to user, rotate syringe 90° clockwise into locked position.
6. Advance needle by fully advancing white adapter of needle and lock in place with luer fitting. **Note:** If needle does not extend past distal end of catheter or if needle hub is bent inside black adapter, discard device.
7. Prime gel into needle by rotating knob of handle in a clockwise manner until gel visibly exits distal end of needle.
Note: If device does not deploy gel during priming, discard device.

8. Once gel begins exiting distal end of needle, turn knob of handle in a counter-clockwise manner one-quarter turn and fully retract needle.

INSTRUCTIONS FOR USE

1. Advance endoscope in small increments to target site.
2. Insufflate and irrigate targeted area to provide adequate endoscopic visualization then evacuate irrigation.
3. Attach a saline-filled syringe to an endoscopic injection needle.
4. Introduce injection needle into endoscope accessory channel and advance in short increments to target site.
5. Insert injection needle into submucosal layer and inject the desired amount of saline to form a starter bleb.
6. Remove injection needle and insert needle catheter into compatible endoscope accessory channel and advance in short increments to target site. **Note:** Ensure that needle is in fully retracted position. **Note:** If catheter is unable to exit the distal end of the accessory channel while scope is in bent or retroflexed position, straighten scope until catheter is endoscopically visible.
7. Expose needle by fully advancing white adaptor of needle and lock in place with luer fitting. **Note:** If needle does not extend past distal end of catheter, discard device. **Note:** If needle extension is inadequate, gently move the proximal end of the catheter in small increments back and forth to ensure full needle extension length.
8. Insert needle into elevated submucosa (starter bleb) and inject gel by rotating knob of handle in a clockwise manner to achieve desired tissue elevation. **Note:** Some gel leakage may occur. If there is substantial rate of gel leakage, discard device.
9. After desired tissue elevation is achieved, fully retract needle and remove device from endoscope.

Upon completion of procedure, dispose of device(s) per institutional guidelines for biohazardous medical waste.

SYMBOLS: Single use only / RX Only / Sterile-EO / Sterile-Steam

"Manufacturer" symbol

Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105
USA

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CPN 12700/0311



iSnare[®] system – oval snare

Système iSnare[®] - Anse standard
iSnare[®] System – Standardschlinge
Sistema iSnare[®] - laccio standard
Sistema iSnare[®] - Asa estándar
Sistema iSnare[®] - ansa standard
iSnare[®] system - standard slynge
iSnare[®] systeem - standaard poliepsnoerder
iSnare[®] sistemi - standart siner
iSnare[®] 시스템 - 표준 올가미

Reorder No. 00711085 (23g) / 00711086 (25g)

Référence de commande 00711085 (23g) / 00711086 (25g)
Nachbestell-Nr. 00711085 (23g) / 00711086 (25g)
N. di riordino 00711085 (23g) / 00711086 (25g)
Nº de pedido 00711085 (23g) / 00711086 (25g)
N.º de encomenda 00711085 (23g) / 00711086 (25g)
Genbestillingsnr. 00711085 (23g) / 00711086 (25g)
Nabestelnr. 00711085 (23g) / 00711086 (25g)
Yeni Sipariş Numarası: 00711085 (23g) / 00711086 (25g)
주문 번호 00711085 (23g) / 00711086 (25g)

iSnare[®] system – hexagonal snare

Système iSnare[®] - Anse hexagonale
iSnare[®] System – Hexagonalschlinge
Sistema iSnare[®] - laccio esagonale
Sistema iSnare[®] - Asa hexagonal
Sistema iSnare[®] - ansa hexagonal
iSnare[®] system - sekskantet slynge
iSnare[®] systeem - zeshoekige poliepsnoerder
iSnare[®] sistemi - altigen siner
iSnare[®] 시스템 - 육각 올가미

Reorder No. 00711088 (25g) / 00711089 (23g)

Référence de commande 00711088 (25g) / 00711089 (23g)
Nachbestell-Nr. 00711088 (25g) / 00711089 (23g)
N. di riordino 00711088 (25g) / 00711089 (23g)
Nº de pedido 00711088 (25g) / 00711089 (23g)
N.º de encomenda 00711088 (25g) / 00711089 (23g)
Genbestillingsnr. 00711088 (25g) / 00711089 (23g)
Nabestelnr. 00711088 (25g) / 00711089 (23g)
Yeni Sipariş Numarası: 00711088 (25g) / 00711089 (23g)
주문 번호 00711088 (25g) / 00711089 (23g)

INSTRUCTIONS FOR USE

Instructions d'utilisation
Gebrauchsanweisung
Istruzioni per l'uso
Instrucciones de uso
Instruções de Utilização
Brugsanvisning
Gebruiksaanwijzing
Kullanım talimatları
사용 설명서



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5976 Heislley Road
Mentor, OH 44060 USA

phone +1 440 / 639.4494

fax +1 440 / 639.4495

email global@usendoscopy.com

www.usendoscopy.com





Intended Use:

- The iSnare[®] system is a 3.0mm, dual lumen device providing both needle injection and monopolar electrocautery polypectomy snare capability within a single catheter device. The device is indicated for the injection of media for submucosal lift of polyps or other mucosal lesions within the gastrointestinal tract using direct visualization through a flexible front viewing endoscope prior to electrosurgical excision and for the infusion of fluid for clearing the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post polypectomy bleeding, and tattooing of sites for future surveillance or surgical purposes. The dual lumen device provides the user freedom from intra-procedural accessory device exchange during endoscopic gastrointestinal procedures. This device is compatible with Olympus style active cords.

Warnings and Precautions:

General Warnings:

- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to complications, hazards and techniques prior to the performance of any endoscopic procedure.
- A thorough understanding of the technical principles of diathermic energy, as well as clinical applications and associated risks, is necessary before using this device.
- To ensure patient safety, inspection of the active cord and the electrosurgical generator, as well as knowledge of proper settings and use, must precede use of this device.
- Consult the electrosurgical generator manufacturer's instruction booklet for proper settings and use of the active cord and the generator.
- Care must be exercised when using electrocautery instruments to minimize the risk of patient injury. Safe and effective cautery is dependent on factors under the control of the user, as well as equipment design and its adequate inspection and maintenance.
- In order to ensure that the insulating properties of the device are not compromised, do not exceed the maximum rated recurring peak voltage stated for each high frequency mode (see chart below).

High Frequency Mode	Maximum Rated Recurring Peak Voltage
Cut	1200 Volts
Coagulation Burst	2100 Volts
Coagulation Spray	5000 Volts

- Polypectomy should not be attempted unless proficiency in technique has been developed by the clinician.
- The correct method of polyp resection will depend upon the size of the polyp, as well as the type of polyp (e.g. pedunculated or sessile).
- Polypectomy procedures have been associated with complications such as burning or perforation of the intestinal wall.
- Injection with an endoscopic injection needle should not be attempted unless proficiency in technique has been developed by the clinician.
- 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.
- The iSnare[®] system is not intended for reuse. US Endoscopy does not take responsibility for the safety and effectiveness of this disposable medical device following reprocessing, remanufacturing, and/or resterilization by any institution, practitioner or third party.

Device Handling Warnings:

- This device is not designed for use in a side viewing duodenoscope.
- Do not attempt to actuate this device with the catheter in a straightened position. The injection needle has been engineered and manufactured with a specific "preload" that is necessary to assure a full projection and full retraction of the injection needle from the injection needle stop when in tortuous configurations. If the device is actuated with the catheter in a straightened position, the "preload" may cause the injection needle's inner catheter to collapse and not allow for adequate injection.
- Short strokes, 1"-1.5" (2.5cm – 3.8cm) in length, are recommended throughout device passage to avoid catheter kinking.
- Insertion and extraction forces during passage and withdrawal of the device through the endoscope's accessory channel will be greater in a 3.2 mm channel (e.g. pediatric endoscope) compared to the forces experienced in 3.7mm or larger channel diameter (e.g. therapeutic endoscope) due to the 3.0mm diameter of the catheter.
- The user may experience increased resistance when passing and withdrawing the device through the endoscope's accessory channel when the endoscope is in an articulated configuration.
- Do not use excessive pulling force when removing the device from the endoscope. Excessive pulling force may stretch and/or damage the device (e.g. alter the injection needle position or projection length or cause the needle to pierce the catheter) or damage the endoscope, and may result in accidental injury to the patient or clinician.
- Before removing the device from the endoscope or significantly retracting device within endoscope, ensure that the tip of the endoscope is in a straight and unarticulated configuration. Use minimal pulling forces when removing the device.
- Before reinserting the device into the endoscope, check to confirm that the needle and snare function and that they are in a retracted position.

Injection and Cautery Warnings:

- The black distal tip of the injection needle catheter is designed to enhance injection needle performance. Do not tamper with or attempt to remove the distal tip.
- The injection needle is compatible with the following medical substances and solutions: Sodium Morrhuate, Sodium Tetradecylsulfate, Ethanolamine Oleate, Epinephrine, Botox, Polidocanol, Ethanol, Sotradecol, Absolute Alcohol, India Ink, Hypertonic Saline, and Staining Media. The compatibility of other substances has not been verified and therefore should not be attempted.
- When handling this device, always be aware of the device's distal tip and visually confirm that the injection needle is fully retracted into the catheter to minimize the risk of accidental injury to the patient or clinician.
- The injection needle should be fully retracted into the catheter during use of the snare to prevent inadvertent injury to the mucosa.
- The snare should be fully retracted into the catheter during use of the injection needle to prevent inadvertent injury to the mucosa.

Contraindications:

Contraindications include those specific to any endoscopic procedure, use of electrocautery, uncooperative patients, and patients with coagulopathy. Consultation with appropriate medical personnel regarding use of this device in patients with an implanted electronic device is the responsibility of the user.

The iSnare[®] system is a dual handle device. Manipulation of the injection needle and/or snare is achieved using independent handle controls. The device is shipped in a prepackaged position with the polypectomy snare loop deployed and the injection needle retracted. The diathermic finger ring handle controls the snare loop. The luer lock handle controls the injection needle.

Directions for Use

1. Prior to clinical use you should familiarize yourself with the device.
 - Read the "Warnings and Precautions" and the "Directions for Use." Review the diagrams.
2. Open the sterile package and visually inspect the device. If damage is evident, do not use the device.
3. The black distal tip of the injection needle catheter is designed to enhance injection needle performance. Do not tamper with or attempt to remove the distal tip.
4. Gently release and remove the banding straps that secure the catheter.
5. Uncoil the entire device. Do not attempt to manipulate the device handles until after the catheter has been carefully uncoiled and you are draping the device in a "U" shaped configuration, holding the proximal device end in one hand, and the distal device end in the opposite hand.
6. With the device in this position, retract the finger ring handle to withdraw the polypectomy snare loop back into its protective catheter.
7. To actuate the injection needle, advance and release the proximal luer lock handle and visually observe the injection needle projecting and retracting from the distal end of the device. The spring loaded handle assists in injection needle retraction, but visual observation of full injection needle retraction is always recommended in order to minimize the risk of damage to the endoscope or accidental injury to the patient or clinician.
8. Following recommended medical techniques, perform EGD or Colonoscopy.
9. To prepare the injection needle for use, the injection needle should be locked in the out position by:
 - Gently pressing the proximal luer until it meets the handle luer and then slowly twist clockwise until the two luers are fully engaged (see Fig. 1; Fig. 1A shows distal tip with injection needle deployed).
 - The injection needle assembly should then be purged of air with injection media.
 - The injection needle should be unlocked/retracted into its catheter by gently twisting the proximal luer counterclockwise until the two luers are fully disengaged (see Fig. 2; Fig. 2A shows distal tip with injection needle retracted).
10. To prepare the polypectomy snare for use, securely attach an Olympus style active cord to the device's diathermic handle. The electrosurgical generator should be set to the proper settings that allow resection of the polyp with controlled hemostasis. Consult the electrosurgical generator manufacturer's instruction booklet for proper use of the generator, proper settings, use of the active cord, and the proper application and position of the patient return electrode.
11. After endoscopic identification of the desired injection/infusion site, pass the device (with injection needle and snare fully retracted) through the accessory channel of the endoscope and proceed with injection/infusion of appropriate media using approved medical techniques until desired results are accomplished.
12. The injection needle should then be released and fully retracted back into its catheter. Visual observation of full injection needle retraction is always recommended in order to minimize the risk of damage to the endoscope or accidental injury to the patient or clinician.
13. Open the snare loop by advancing the finger ring handle until it stops. Confirm that the snare loop is fully open via endoscopic observation (see Fig. 3).
14. Position the snare loop and resect the polyp using proper surgical technique.
15. Before removing the device from the endoscope or significantly retracting device within endoscope -
 - a. ensure that the snare loop as well as the injection needle are fully retracted into the catheter in order to minimize the risk of damage to the device and the endoscope, or injury to the patient and the clinician (see Fig. 4).
 - b. ensure that the tip of the endoscope is in a straight and unarticulated condition. Use minimal pulling forces when removing the device.
16. Before reinserting the device into the endoscope, check to confirm that the needle and snare function and that they are in a retracted position.
17. Once the polyp has been satisfactorily resected, the polyp fragment(s) should be removed and the specimen(s) 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: April 2010

Warning:

An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

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Olympus[®] is a registered trademark of Olympus Optical Co., Ltd.

Made in the U.S.A.

FIG. 1

ADVANCE AND TWIST
LUER LOCK CLOCKWISE
TO DEPLOY AND LOCK
INJECTION NEEDLE IN
THE OUT POSITION

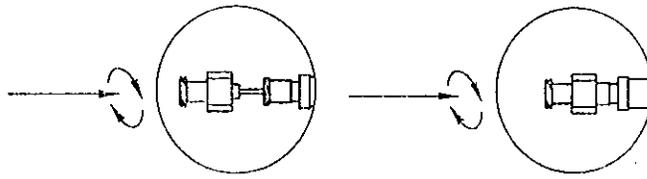


FIG. 1A

BLACK DISTAL TIP
INJECTION NEEDLE
DEPLOYED

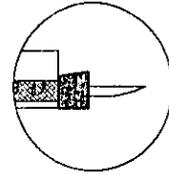


FIG. 2

TWIST LUER LOCK
COUNTERCLOCKWISE TO
UNLOCK AND RETRACT
INJECTION NEEDLE

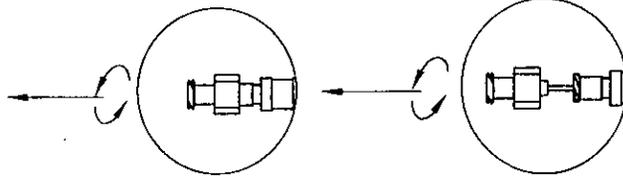


FIG. 2A

BLACK DISTAL TIP
INJECTION NEEDLE
RETRACTED

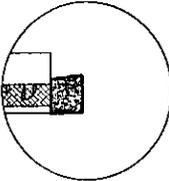


FIG. 3

SNARE DEPLOYED, INJECTION NEEDLE RETRACTED

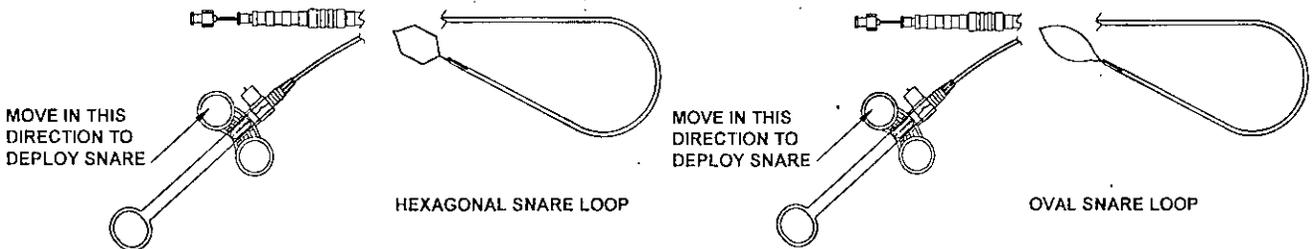
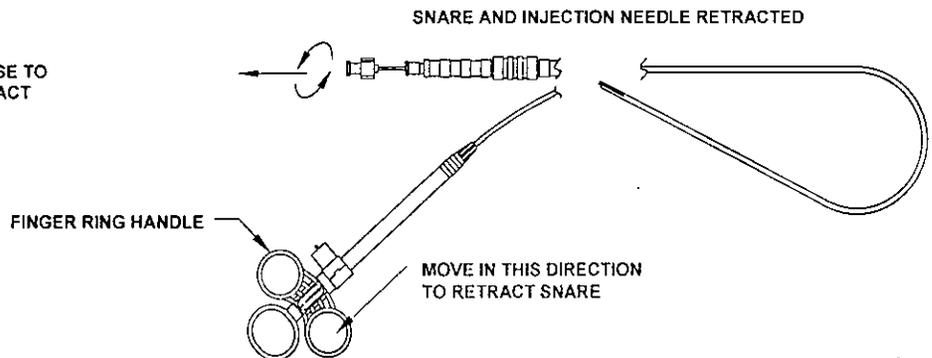


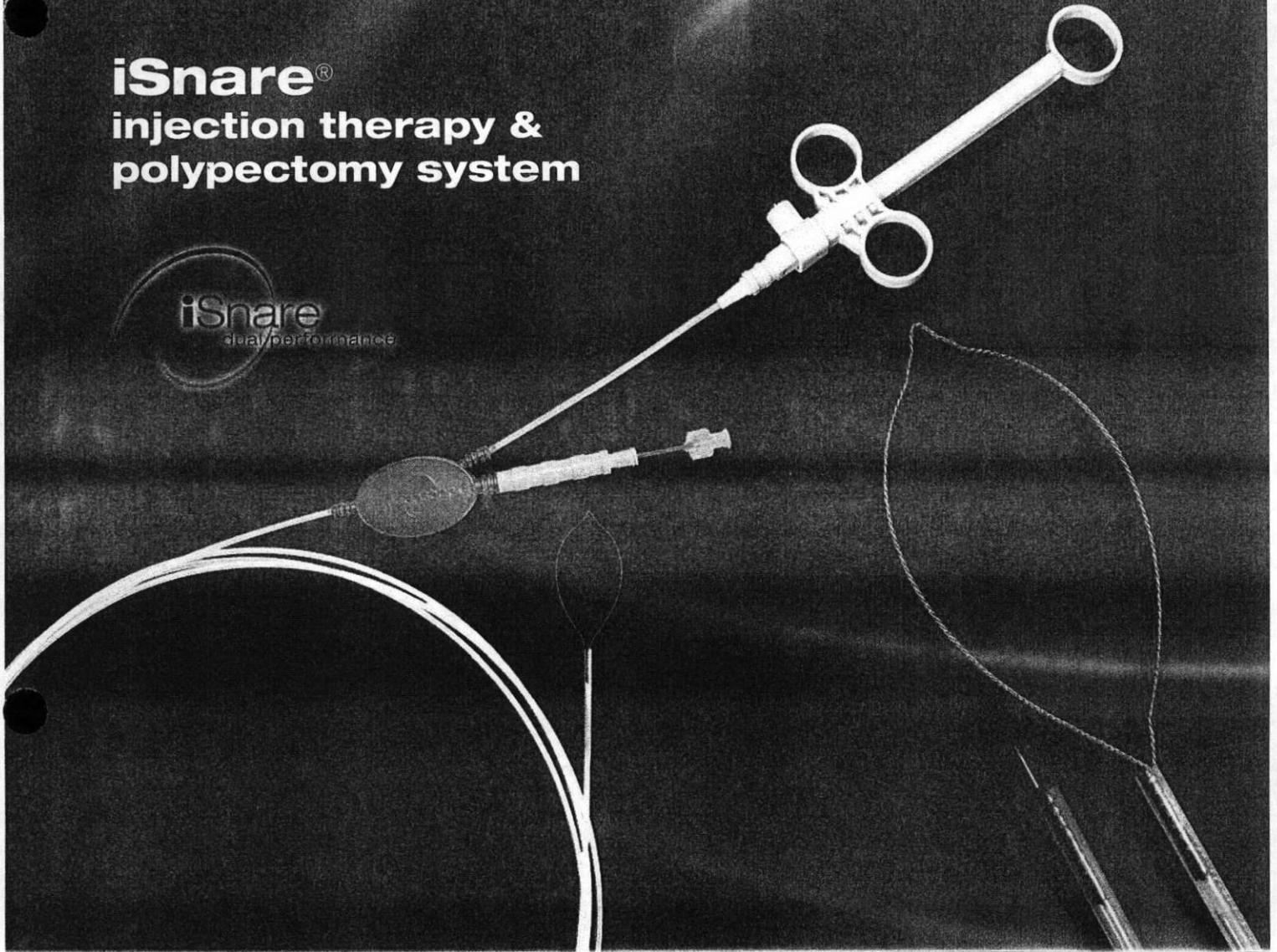
FIG. 4

TWIST LUER LOCK
COUNTERCLOCKWISE TO
UNLOCK AND RETRACT
INJECTION NEEDLE



iSnare[®]
injection therapy &
polypectomy system

iSnare
clear performance



US endoscopy

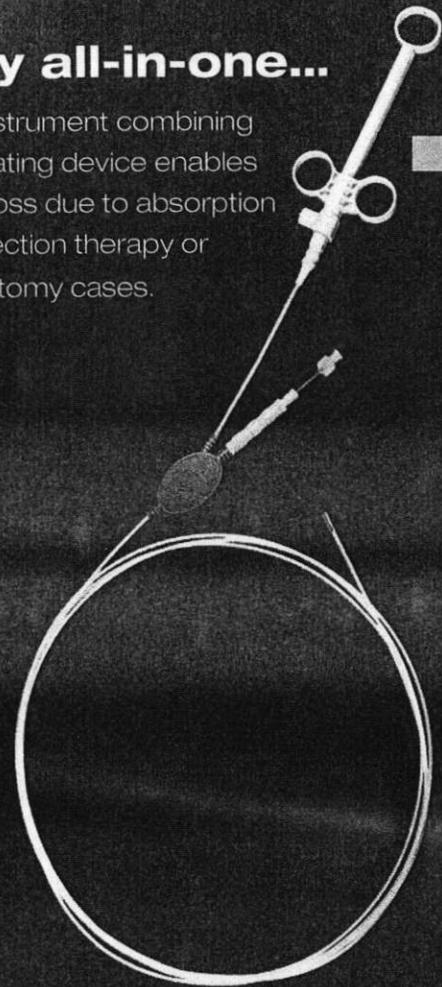
listening...and delivering solutions[™]

Injection therapy and polypectomy all-in-one...

The iSnare[®] device from US Endoscopy is a unique, multi-functional instrument combining injection needle and polypectomy snare technologies. This dual operating device enables polypectomy immediately following saline injection, minimizing "bleb" loss due to absorption or dissipation. The iSnare[®] device also allows for direct hemostatic injection therapy or supplemental injections during large or difficult saline assisted polypectomy cases.

The iSnare[®] device's unique design...

- Features alternating injection needle and polypectomy snare operated by a multi-functional handle
- Facilitates immediate injections in response to bleb absorption/dissipation or bleeding
- Minimizes wasted procedural time - inject or snare at anytime throughout the procedure without device exchange while maintaining scope position
- Features a spring-loaded, luer lock handle for consistent needle projection and retraction



The iSnare[®] device can be utilized for all of the following endoscopic needs: cleansing, applying dye or stain during chromoendoscopy, SAP (saline assisted polypectomy), EMR (endoscopic mucosal resection), hemostatic injection and adherent clot removal, injection therapy, tattooing pre- or post-polypectomy, and any other procedure requiring injection therapy and snare resection techniques.

For more information on the iSnare[®] device, contact US Endoscopy today.

product number	description	needle gauge	needle length	snare size	sheath diameter	sheath length	active cord connector	units/box
00711086	iSnare [®]	25	5mm	2.5 x 4.0cm	3.0mm	230cm	Olympus	5 units/box

US endoscopy

*listening...and delivering solutions**

5976 Heisley Road
Mentor OH 44060

phone 440 / 639.4494

fax 440 / 639.4495

customer service 800 / 769.8226

www.usendoscopy.com

760205 Rev. C

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iSnare[®] U.S. Patent Number 6,814,739, 5,643,283 and other patents pending
Olympus® is a registered trademark of Olympus Optical, Inc.

us endoscopy

home / endoscopy / polypectomy and tissue acquisition / isnare system / **isnare system - oval snare**

iSnare system - oval snare



The iSnare® system is ideal for endoscopic mucosal resection and saline assisted polypectomy. This multi-functional device features an alternating injection needle and polypectomy snare which eliminates the need for intraprocedural device exchange.

Other benefits of this unique system include:

- Enables immediate injections in response to bleb absorption/dissipation or bleeding
- Helps maintain scope positioning throughout the procedure
- Minimizes wasted procedural time - inject or snare at any time throughout the procedure without device exchange
- Spring loaded, luer lock handle ensures consistent needle projection and retraction
- Available in 23 or 25 gauge needle

Related Documents

- | | |
|-----------------|----------------------------|
| IFU | Case Report: 1 |
| Case Report: 2 | Case Report: 3 |
| Case Report: 4 | Spec Sheet (International) |
| Spec Sheet (US) | Product Highlights |

Videos & Animations

[Download for mobile](#)
[Download Instructions](#)

- iSnare® system: saline assisted polypectomy animation
- iSnare® system: piecemeal resection of large, sessile polyp
- iSnare® system: removal of gastric inflammatory/hyperplastic polyps
- iSnare® system: EMR at Amsterdam Live 2009

Specifications

product number	sheath diameter	length	approximate snare size	active cord connection	needle	units/box
00711085 	3mm	230cm	2.5x4.0cm	Olympus style	23 gauge x 5mm	5
00711086 	3mm	230cm	2.5x4.0cm	Olympus style	25 gauge x	5



This product has been manufactured not to include latex.

Related Products:

- eTrap polyp trap
- iSnare system - hexagonal snare
- Roth Net retriever - polyp
- Roth Net Platinum retriever - polyp

Indications for Use Form

Indications for Use

510(k) Number (if known): k111495

Device Name: Cook GI Endoscopic Injection Gel Kit

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Indications for Use Form

Indications for Use

510(k) Number (if known): unk

Device Name: TBD

Indications for Use:

This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

ATTACHMENT F: 510(k) Summary

SPONSOR: Wilson-Cook Medical, Inc. /Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105

CONTACT/SUBMITTER: Marge Walls-Walker
Senior Regulatory Specialist: Engineering
[336] 744-0157 Ex. 6290

DATE OF SUBMISSION: May 26, 2011

DEVICE: Gastroenterology Injection Needle

Trade Name: Cook GI Endoscopic Injection Gel Kit
Common Name: GI Endoscopic Injection Needle
Classification: GI/GU Injection Needle, Class II FBK
21 CFR § 876.1500

PREDICATE DEVICES: US Endoscopy Dual Lumen Injector Needle Snare
(k040961)
Cook Endoscopic Ultra Ultrasound Needle
(k083330)

TENDED USE: This device is indicated for sub mucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device

DEVICE DESCRIPTION: The proposed Cook Device is assembled by the end user from three component pieces: a handle with a threaded piston and directional arrow, a sterile needle cannula with an attached pressure gauge to track pressure in the event of needle kinks/bends in the tortuous GI anatomy and a sterile 10 cc syringe filled with a mixture of sterile water and sodium CMC. Blue colorant may or may not be added to enhance endoscopic visibility. After creation of a starter bleb below affected tissue, the gel is then injected into the starter bleb. The bleb will then stay elevated from the muscle layer to allow for endoscopic dissection or resection with a separately supplied endoscopic electro-surgical device. After excision and retrieval of affected tissue, the bleb will dissolve and pass out of the body naturally.

COMPARISON OF CHARACTERISTICS:

We believe the proposed device to be substantially equivalent to the named predicates in terms of Intended Use, Indications for Use, performance characteristics tested, needle gauge, principle of operation and biocompatibility. No electrosurgical instrument is provided with the subject device to allow for the excision, but the removal of the bleb can be accomplished using one of the many existing technologies available.

PERFORMANCE DATA:

Pre-clinical testing verified the biological safety of the injection media and validated the performance capabilities of the GI Endoscopic Injection Gel Kit to meet its design criteria through a series of bench and animal testing. The IFU suggests a preliminary injection of saline to begin the bleb to reduce the inherent risk of all injection needles for perforation/injection into the muscularis. The subject device is meant to complement existing technologies for excision of GI tract tissue by creation of a visible bleb using a viscous injectate that is easily available, and effective. The viscosity of the subject gel overcomes the limitation of injection of saline and other low viscosity materials with respect to time the bleb remains elevated from the muscularis and other mechanical mucosal separation techniques that may result in muscle layer involvement.

Records processed under FOIA Request # 2013-8495; Released by CDRH on 10-05-2015



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name H. HERRERA
Subject: 510(k) Number K111495
To: The Record

Please list CTS decision code SE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NC NSE call for PMAs
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓

Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC. ✓

Regulation Number	Class*	Product Code
21 CFR 876.1500	II	FBK

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:	<i>[Signature]</i> (Branch Chief)	UDB (Branch Code)	7/15/2011 (Date)
Final Review:	<i>[Signature]</i> (Division Director)		7/18/11 (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

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

K111495

Date: July 15, 2011
To: The Record
From: Hector H. Herrera, M.D., M.P.H.
Office: ODE
Division: DRGUD/ULDB

510(k) Holder: Wilson-Cook Medical, Inc./Cook Endoscopy
Device Name: Cook GI Endoscopic Injection Gel Kit
Contact: Marge Walls-Walker Senior Regulatory Affairs Specialist
Phone: 336-744-0157 x 6290
Fax: 336-201-5024
Email: marge.walls-walker@cookmedical.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Cook GI Endoscopic Injection Gel Kit into interstate commerce. The device is an Endoscopic kit: Injection Needle for use in the GI and Urology, the needle is used to assist in the dissection of tumors by injecting a solution under the submucosa to lift it away from the muscle so the lesion can be removed as a whole (endoscopic submucosal resection ESD). This procedure is normally performed with saline and the predicate kits provide an unfilled syringe. This kit provides a prefilled syringe containing a (b) sodium carboxymethylcellulose.

A consultation was requested to Angela Krueger (regulatory advisor) regarding the use of the carboxymethylcellulose, in this device; the answer was that CDER and OCP did not have any concerns, the use is not acting as a drug it is a device for the current indication.

My recommendation is: that: The Cook GI Endoscopic Injection Kit is substantially equivalent to predicate devices with respect to indications for use, materials of construction and technological characteristics

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, Standards Form.

III. Device Description

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

The device contains three (3) components:

- The handle with threaded plunger (GEL-H)
- The syringe filled with (b) sodium carboxymethylcellulose (CMC) dissolved in sterile water with blue tint (GEL-S)
- The endoscopic injection needle with pressure gauge (GEL-N)

The injection needle is identical to the 19 gauge of the cleared (k083330 Cook ECHO), with respect to materials of construction of the stainless needle and blue PEEK sheath. The needle lengths are identical with ~75 cm of the ECHO needle passing through the handle of the device. The Gel needle extends only 1 cm out of its sheath vs (0-8 cm of predicate) due to the clinical technique associated.

The needle sheath length is different (~220 cm for subject device and ~142cm for the ECHO) due to the termination of the sheath at the base of the ultrasound handle as opposed to the sheath running the entire length of the subject needle.

The proximal end of the needle terminates in male/female Luer-type connection that control extension and retraction of the distal needle.

The connection is then adapted into and through the pipe fitting using nylon and Deldrin connectors.

Perpendicular to the proximal end of the needle is the 3000 psi MPa (max) stem-mount pressure gauge, integrated so that the physician can observe system pressure during procedure. During injection of the Gel system, builds pressure (force/area) by pushing a viscous material through a narrow tube (needle) over 220 cm length, the IFU instructs that the maximum pressure during use not exceed 1500 psi, which would indicate a bent or compromised needle.

The blue syringe contains the GI Endoscopic Injection Gel is identical in materials of composition manufacturing and vendor as K042691. The primary difference is that the predicate is distributed unfilled, and the subject device comes prefilled with a CMC solution capped at both ends, then steam sterilized. Caps are later removed for connection of the system. The pre-mixed solution of (b) weight to volume CMC, sterile water and .001.003g/175 mL (0.0006-0.0017%) indigo carmine FD&C blue tint. The tint allows easier endoscopic visualization during the dissection.

The Carboboxymethylcellulose (CMC) is used to adhere and dental cushion dentures; is used also as dissolvable Gels for preventing ureteral Stone Migration during Lithotripsy.

The colorant is on the list of FDA chemicals recognized as safe (GRAS), is one of the nine synthetic color additives permitted for direct addition into food. Both CMC and FD&C Blue No. 2 have no known pharmacologic actions and are considered to be safe and non-toxic. The device is placed in the externally communicating category with tissue contact with limited (24 hours) contact duration.

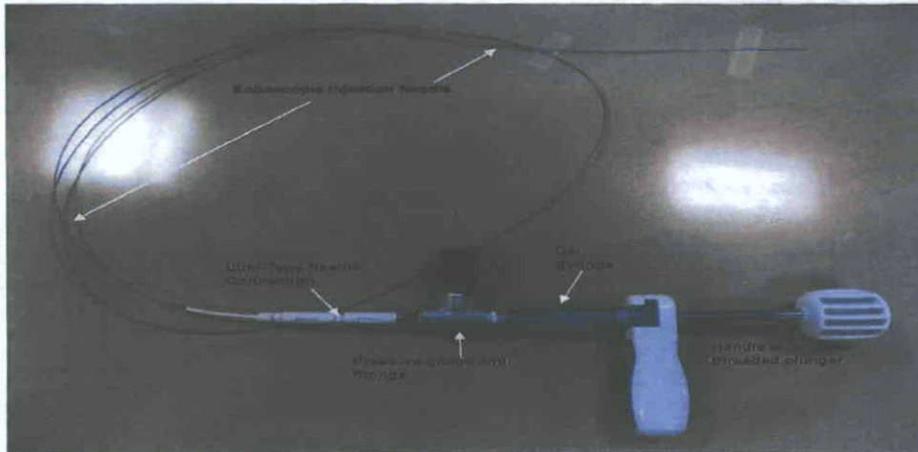


Figure 1: Cook GI Endoscopic Injection Gel Kit

Ingredient	Chemical Abstract Number (CAS)	Concentration in Device
CMC	9004-32-4	3.00% (w/v)
FD&C Blue No 2	B60-22-0	0.001-0.003 g/175 mL

Typically, about 5 mL of the agent is injected per lesion that is 20 mm or less, the lifting agent would be considered to have limited contact duration (less<24 hours) with tissue contact.

The only two differences with the predicate:

a. The Caarboxymethyl cellulose for injection below the mucosa is well known in varying concentrations as a medical device across medical disciplines; but this gel is not implanted or absorbed into the muscularis and sloughs through the GI tract and out of the body once the affected tissue is removed.

b. The Moist Heat (Steam) Sterilization is a recognized and effective method for sterilization of medical devices like CalMatrix (K041311), Juliese (K060815), and Coaptite (P040047).

IV. Indications for Use

The device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

K083330 is used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspiration of submucosal lesions.

K040961 has the same indications, but is used with an Olympus Microvative active cord for the injection of media for submucosal lift of polyps or other mucosal lesions.

V. Predicate Device Comparison

Parameter	Cook Endoscopy ESD Subject Device	US Endoscopy K040961	Cook Endoscopy ECHO K083330
Intended Use	Lift of polyps or other gastrointestinal mucosal lesions prior to excision with snare or endoscopic device	For injection of media for submucosal lift of polyps or other lesions, prior to electrical excision	For delivery of injectable material into tissue and fine needle aspiration of submucosal lesions (with ultrasound)
Direction of Use	Disposable, Single Use	Disposable, Single Use	Disposable, Single Use
Needle Gauge	19 ga	25 ga	19, 22, 25 ga

Needle Material	302/304 Stainless Steel	302/304 Stainless Steel	302/304 Stainless Steel
Needle length extended	1 cm non adjustable	0.5 cm non adjustable	0-8 cm adjustable
Catheter (sheath) material	Blue PEEK	Polymer	Blue PEEK
" " diameter	220.3 cm +/- 3 mm	230 cm	142.2 cm +/- 2 mm
Endoscope compatibility channel	2.8 mm access channel non US	3.7 access channel non ultrasound	2.0 mm access channel ultrasound
Handle locking mechanism	Luer-type	Luer-type	Luer-type
Supplied sterile	Yes EO-needle, steam gel	Yes EO	Yes EO
Snare or excision device	No	Yes	No

**K040961 US Endoscopy Group Dual Lumen Injector Needle Snare
K083330 Cook ECHOTIP ULTRA ULTRASOUND NEEDLE**

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). These including: Precautions, Contraindications, potential Complications, and Warnings regarding no to use as a bulking agent and not to exceed the recommended working pressure of 1500 psi.

The labeling is similar to the labeling of the predicates.

VII. Sterilization/Shelf Life/Reuse

Sterilization Method	Ethylene Oxide
Validation Method	Consistent with half-cycle (ISO11135-1)
Maximum levels of residuals	Ethylene Oxide 4mg/day Ethylene Chlorohydrin 9mg/day ISO 10993-7 (2008)
Sterility Assurance Level	10 ⁻⁶
Syringe sterile via moist heat	Consistent with half-cycle (ISO 17665-1)
Description of Packaging	Outer layer of polyester over a layer of adhesive which joins to the inner layer of polyolefin. The outer layer prevents adhesions to heat seal platens. Pouches are sealed using validated sealers
Sterility Assurance Level	10 ⁻⁶
Accelerated Aging Parameters 38 days ASTM F 1980	Temperature 55°C +/- 2 °C Relative Humidity <20%
Shelf Life Maximum 1 year	

The use of the Moist Heat Sterilization cycle was validated according to ISO 17665 with a validated SAL 10⁻⁶. All verification and validation activities used sterile devices to assure that sterilization did not affect the viscosity of the gel or operational capabilities of the assembled device.

VIII. Biocompatibility

(b)(4)



(b)(4)



IX. Software NONE

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety NONE

XI. Performance Testing – Bench

(b)(4)



XII. Performance Testing – Animal

(b)(4)



XIII. Performance Testing – Clinical

(b)(4)



XIV. Substantial Equivalence Discussion

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

- Describe the new technological characteristics: even though the predicate uses the same kind of needle, one uses media, the other uses injectable material and an empty syringe, the subject device comes in a syringe prefilled with (carboxymethylcellulose and indigo carmine), and is capped at both ends, then steam sterilized. The syringe is identical in materials of composition, manufacturing methods and vendor as the syringe of predicate (K042691). Perpendicular to the proximal end of the needle is a 3000 psi, 21 MPa (Max) stem-mount pressure gauge integrated into the gel system so the physician can observe the system pressure during the procedure.

(b) (4)



XVI. Contact History

On July 12/2011, at 9:50 am I called Marge Walls-Walker (Senior Regulatory Affairs) at (336) 744-0157 and informed her that additional information was needed: a) Kit certification and b) Form FDA 3654 Utilization of Standards, she promised to send them before Friday 15 by e-mail.

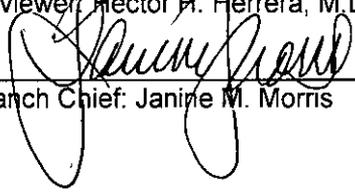
On July 13, I received the Kit Certification for the 510(k), and on July 14 received the Standards Data Reports, this satisfactorily resolved the deficiencies (additional information) submitted to the Company on July 12, 2011.

XVII. Recommendation SE

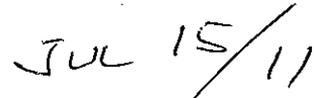
Regulation Number: 21 CFR 876-1500
Regulation Name: Endoscopy and Accessories
Regulatory Class: Class II,
Product Code: FBK



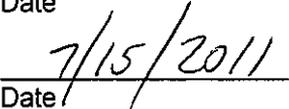
Reviewer: Hector H. Herrera, M.D.



Branch Chief: Janine M. Morris



Date



Date

Herrera, Hector H.

From: Walls-Walker, Marge [Marge.Walls-Walker@CookMedical.com]
Sent: Monday, July 18, 2011 1:43 PM
To: Herrera, Hector H.
Subject: RE: K111495
Importance: High
Attachments: Indications for Use Form Rev 2.docx

Dr. Herrera,

Attached, please find the "Indications for Use Form " for k 111495 with the corrections/additions you requested. Please don't hesitate to contact me with any further questions and/or concerns.

I will send a paper copy of the revised Indications for Use Form to the Document Mail Center to be forwarded to your attention.

Best Regards,
Marge

Marge Walls-Walker

Senior Regulatory Specialist: Engineering
COOK Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105
336. 744.0157 ext 6290
336. 201.5024 (fax)
www.cookmedical.com

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From: Herrera, Hector H. [mailto:Hector.Herrera@fda.hhs.gov]
Sent: Monday, July 18, 2011 12:49 PM
To: Walls-Walker, Marge
Subject: K111495

Hi Marge,

Due to the fact that the Indications for Use Form submitted had a TDB instead of the full name of your device, it is needed and has to be fill by the Submitter, please email me a new form including the number of the 510(k) K111495.

Also please mark the Prescription Use space.

This will be the last (I hope) for the final clearance decision.

Thanks

Hector H. Herrera, M.D., MPH
Medical Officer. ULDB
7066 Room G212
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Morris, Janine M.

From: Krueger, Angela C
Sent: Friday, June 10, 2011 2:16 PM
To: Morris, Janine M.
Subject: FW: question on drug/device issue

Janine - we are okay with proceeding. CDER and OCP don't have concerns. Everyone agrees that for this use, it's not acting as a drug.

Thanks,
Angie

From: Suliman, Ayoub
Sent: Friday, June 10, 2011 2:12 PM
To: Krueger, Angela C; OC Combination Products
Cc: Hayes, Leigh
Subject: Re: question on drug/device issue

Yes, it's a device for this indication.

From: Krueger, Angela C
Sent: Friday, June 10, 2011 01:32 PM
To: Krueger, Angela C; Suliman, Ayoub; OC Combination Products
Cc: Hayes, Leigh
Subject: RE: question on drug/device issue

Ayoub, can you confirm that we don't have an outstanding drug issue here? I didn't want to proceed without your concurrence. Thanks!

From: Krueger, Angela C
Sent: Tuesday, June 07, 2011 11:29 AM
To: Suliman, Ayoub; OC Combination Products
Cc: Hayes, Leigh
Subject: Re: question on drug/device issue

Thanks Ayoub. Do you have concerns with the use of the drug for the proposed use? If we are in agreement that this has a device mode of action, we don't have an outstanding drug issue, correct?

From: Suliman, Ayoub
Sent: Tuesday, June 07, 2011 11:23 AM
To: OC Combination Products; Krueger, Angela C
Cc: Hayes, Leigh
Subject: RE: question on drug/device issue

I agree that this product appears to have a device mode of action same as the gelfusine and endocushion products assigned to CDRH.

To answer Angie's question, sodium carboxymethylcellulose and hydroxypropyl methylcellulose at 0.2 to 2.5 % are GRAS demulcent ingredients in the OTC monograph for ophthalmic drug products. Both ingredients are also GRAS under OTC monograph for laxative (bulk-forming) drug products. Hydroxypropyl methylcellulose is approved under NDA for the treatment of dry eye syndrome. Obviously, these approved uses in CDER are different from the proposed use under the 510(k).

Ayoub Suliman
Product Jurisdiction Officer
FDA/Center for Drug Evaluation and Research
(301) 796-0630

From: OC Combination Products
Sent: Monday, June 06, 2011 5:07 PM
To: Krueger, Angela C; Suliman, Ayoub
Cc: Hayes, Leigh; OC Combination Products
Subject: RE: question on drug/device issue

This sounds similar to the gelofusine product question (see attached) we had not too long ago. We also have an RFD for Endocusion, which contained hydroxypropyl methylcellulose (linked). Both were assigned to CDRH.
http://eroom.fda.gov/eRoom/OC3/FDAOfficeofCombinationProducts/0_1bc9

Provided all it's doing is lifting a lesion, and CDER is in agreement, OCP has no jurisdiction concerns.

<< Message: FW: Gelofusine >>

Kristi

Mon and Wed @home 301-926-0895

From: Krueger, Angela C
Sent: Monday, June 06, 2011 4:48 PM
To: Suliman, Ayoub; OC Combination Products
Cc: Hayes, Leigh
Subject: FW: question on drug/device issue

Hi all,

Could you take a look at the information below and let me know whether you think there is a jurisdiction issue? Ayoub - do you have anything over in CDER with (b) sodium carboxymethylcellulose?

To me it seems like this might still be providing a mechanical/physical function, but want to see if anyone else has questions.

Thanks,
Angie

From: Morris, Janine M.
Sent: Monday, June 06, 2011 9:14 AM
To: Krueger, Angela C
Cc: Morris, Janine M.
Subject: RE: question on drug/device issue

Yes that is what it sounds like to me as well but just wanted to be cautious as I didn't recognize the agent they are including in the kit. The indication for use is:

"This device is indicated for submucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device."

The predicate indication for use is:

"The dual lumen Injector Needle Share is indicated for use with an Olympus or Microvasive active cord for the injection of media for submucosal lift of polyps or other mucosal lesions, using direct visualization, through a flexible endoscope, prior to electrosurgical excision and for the infusion of fluid for clearing away the field of view, applying dye spray, clot removal, injection of hemostatic agents to control post-polypectomy bleeding, and tattooing of sites for future surgical purposes."

Janine M. Morris, Branch Chief

Urology and Lithotripsy Devices Branch
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WO66 Room G208
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
office phone: (301) 796-5706
blackberry: (301) 318-9659
janine.morris@fda.hhs.gov

From: Krueger, Angela C
Sent: Friday, June 03, 2011 6:23 PM
To: Morris, Janine M.
Subject: RE: question on drug/device issue

Hi Janine,

This sounds like it is serving a mechanical/physical function in terms of lifting away from the muscle. I will touch base with the CDER jurisdiction officer to make sure they wouldn't consider this a drug. Can you send me the indication?

Thanks,
Angie

From: Morris, Janine M.
Sent: Friday, June 03, 2011 2:55 PM
To: Krueger, Angela C
Cc: Morris, Janine M.
Subject: question on drug/device issue

Angie,

I just got a 510k for a simple endoscopic kit for endoscopic submucosal dissection (ESD) in the GI tract. Its basically a injection needle used to assist in the dissection of tumors by injecting a solution under the submucosa and mucosa to lift it away from the muscle so the lesion can be removed as a whole. This is normally done with saline and predicate kits just provide an unfilled syringe. This kit provides a prefilled syringe containing (b) sodium carboxymethylcellulose.

So I am wondering if we need to get a CDER consult for this or if you need to weigh in as to primary mode of action. What do you think? Herb says it is a common solution used in surgery but I have no idea if it is approved for this use. Can you assist?

Janine M. Morris, Branch Chief
Urology and Lithotripsy Devices Branch
Division of Reproductive, Gastro-Renal, and Urological Devices
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janine.morris@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 14971:2007 Medical devices-Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-40

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>
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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 14971:2007 Medical devices-Application of risk management to medical devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex I	SECTION TITLE Guidance on risk analysis process for biological hazards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * All factors as identified in 1.2.1: physical and chemical characteristics of the materials, history of use and human exposure data, existing toxicological and biological safety data on product/component materials and test procedures		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>* 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.</p>		
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and roui

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-261

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>
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 17665-1:2006 Sterilization of Health Care Products-Moist Heat-Part 1: Requirements for the development, validation and rou		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex D	SECTION TITLE Conservative process definition based on inactivation of reference microorgani	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: D2.2(a)Place biological indicators w/i the product at position(s) where sterilizing conditions are most difficult to achieve Option: D3Partial cycle approach		
DESCRIPTION D.3 Expose load to sterilizing agent under conditions designed to deliver reduced level of treatment to the extent of inactivation of 10 ⁶ microorganism on BI. Identified level of treatment repeated 3X.		
JUSTIFICATION Most suitable sterilization method for Carboxymethylcellulose		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-229

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, 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>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Section 7, X2,X3	SECTION TITLE Accelerated Aging Planning	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Complete assembly aging Parameters: 38 days@55°C +/-2°C and <20% Relative Humidity. The RH value is a deviation from Annex 3 parameters.		
DESCRIPTION The third-party vendor has a default setting of <20% for all accelerated aging which exceeds recommendation in A3, but provides worst-case scenario for test parameter.		
JUSTIFICATION Temperature parameter was dictated by most limiting packaging/sealing configuration (pouch for moist heat sterilization) as recommended by the packaging vendor. Relative Humidity is default as set by aging vendor		
SECTION NUMBER Section 8	SECTION TITLE Post-Aging Testing Guidance	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Functional Testing post accelerated aging		
DESCRIPTION Post Accelerated Age Testing of assembled device detailed in Section 7.2.2 of the submission.		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

ISO 10993-1:2009 Biological evaluation of Medical Devices- Part 1: Eval and testing within a risk management system.

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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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: G95-1: Use of International Standard ISO 10993"Biological Evaluation of Medical Devices Pt 1:....."

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>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

ISO 10993-5:2009 Biological eval.of Medical Devices- Part 5: Tests for in-vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #023 2-153

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: G95-1: Use of International Standard ISO 10993"Biological Evaluation of Medical Devices Pt 1:....."

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>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-5:2009 Biological eval.of Medical Devices- Part 5: Tests for in-vitro cytotoxicity		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 8.2, 8.5	SECTION TITLE Test on Extracts. Determination of cytotox. Introducer Components and Syring	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * IX MEM Elution		
DESCRIPTION Full tests reports attached as Annex in 510(k)		
JUSTIFICATION None needed, per standard recommendations and FDA recognition		
SECTION NUMBER 8.4.1, 8.4.2, 8.5	SECTION TITLE Tests by indirect contact: Agar diffusion, filter diffusion, determination of cyto	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Filtration followed by agarose overlay		
DESCRIPTION Full tests reports attached as Annex in 510(k)		
JUSTIFICATION Feasible test methodology for Carboxymethylcellulose		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement		
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-279

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>

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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>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4.0	SECTION TITLE Requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: 4.2,4.3,4.4.6.2: Device (Needle)categorized as limited exposure		
DESCRIPTION Completed simulated use extraction in similar device.		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour 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: <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 </div> <div style="width: 35%; text-align: right; font-style: italic;"> An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. </div> </div>		

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10: Biological Eval of Med Dev-Part 10: Tests for Irritation and delayed-type sensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#2-152	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: G95-1 "Use of International Standard ISO 10993, Biological Evaluation om Med Dev Part 1: Eval and Tes"		

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		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

ISO 11135-1:2007 Sterilization of health care products: Ethylene Oxide-Part 1: Requirements for the development, validation and....

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

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If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>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</p>	<p>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.</p> <p>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</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 11135-1:2007 Sterilization of health care products:Ethylene Oxide-Part 1: Requirements for the development, validation and...		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex B.1.2(a)	SECTION TITLE Conservative determination of Lethal Rate of Sterilization	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Half Cycle Approach		
DESCRIPTION 3 consecutive cycles run resulting in total inactivation of BIs (10-6) to confirm minimum exposure time. Specified exposure time shall be 2X this minimum time. Cycle of short duration run from which survivors can be recovered to demonstrate adequacy.		
JUSTIFICATION None, the half cycle method was run in accordance with standard recommendations and TIR16, process development and performance qualification for ethylene oxide sterilization- Micorbiological aspects		
SECTION NUMBER 9.3.2.5(b)	SECTION TITLE Validation:Performance Qualification	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option: Product was adopted to existing, validated cycle, no PQ performed for this component (needle)		
DESCRIPTION IQ and OQ previously performed for equipment that delivers same process parameters		
JUSTIFICATION Adopted per TIR 28, Product adoption and process equivalence for ethylene oxide sterilization.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>* 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.</p>		
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July 13, 2011

Traditional 510(k) k111495: Cook GI Endoscopic Injection Gel Kit

Kit Certification for 510(k)s

"If you cannot make the above referenced statement in the second paragraph for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.)."

Kit Component Certification

Component	Clearance/Approval or Pre-Amendment*	Further Processing for Subject Device
Handle	Yes, k 042691*	Repackage/relabel, non sterile
Syringe	Yes, k 042691*	Addition of silicone O-ring and Teflon tape proximal end of plunger, fill with gel, repackage, relabel, sterilize with moist heat vs. EO
Injection Needle	Yes, k 083330*	Minor modification to handle to create gauge interface. EO Sterilized in identical cycle
Gauge	No	Repackage, relabel, sterilize
Sodium Carboxymethylcellulose	Yes, k060815*, P040047, Exempt per 872.3140 21 CFR 182.1745	Mixed in-house with FD&C #2, 100% viscosity verification per batch, syringe fill, package, label and sterilize with moist heat (as sterilized in referenced k). In this application the gel is not intended as an implant or to be resorbable.
FD&C Blue No. 2	Yes, k052900* 21 CFR 82.102	

*Cleared Intended Uses are detailed below:

K 083330: Injection Needle: This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract

K 042691: Syringe and Handle Components: Vertefix™ Radiopaque Bone Cement is indicated for the fixation of vertebral compression fractures during a vertebroplasty procedure.

K 060815: Carboxymethylcellulose: BioForm's Juliesse is indicated as a resorbable implant material to aid in surgical reconstruction as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months.

K052900: FD&C Blue #2: Quill® non-absorbable nylon barbed sutures are indicated for soft tissue approximation excluding closure of the epidermis.

Marge Wallis Walker 7.13.11

Marge Wallis-Walker 7.13.2011

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COMPANY CONFIDENTIAL

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