

K111495

JUL 19 2011

**ATTACHMENT F: 510(k) Summary**

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**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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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.

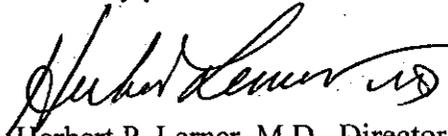
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

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

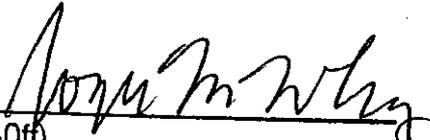
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number k111495