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)

.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 electrosurgical device. After excision and retrieval of affected tissue, the bleb will dissolve and pass out of the body naturally.

COMPARISON OF CHARACTERISITICS:

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K111495