



Food and Drug Administration
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August 17, 2017

Wilson-Cook Medical, Inc. / Cook Endoscopy
Doris A. Hawks
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K171993
Trade/Device Name: Zimmon Needle Knife Papillotome
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: June 30, 2017
Received: July 3, 2017

Dear Doris A. Hawks:

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

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

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

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Benjamin R. Fisher -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K171993

Device Name

Zimmon Needle Knife Papillotome

Indications for Use (Describe)

These devices are used for accessing the common bile duct when standard methods of cannulation have been exhausted.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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009. 510(k) Summary

Zimmon Needle Knife Papillotome

Traditional 510(k) Premarket Notification

June 30, 2017

Applicant Information

Applicant: Wilson-Cook Medical, Inc. /Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, North Carolina 27105
Contact: Doris A. Hawks, Global Regulatory Affairs Specialist
Phone: (336) 744-0157 ext. 396293
Fax: (336) 201-5994

Device Information

Trade Name: Zimmon Needle Knife Papillotome
Common Names: Papillotome, sphincterotome
Classification Name: Endoscopic electrosurgical unit and accessories
Regulation Number: 21 CFR 876.4300
Product Code: KNS
Device Class: Class II
Review Panel: Gastroenterology-Urology

Predicate Device

Name: Wilson-Cook Needle Knife Papillotome
510(k) Number: K972674
Date: Cleared August 15, 1997

Device Description

The Zimmon Needle Knife Papillotome (subject device) is a sterile, single use device compatible with the accessory channel of endoscope. The device consists of a long, thin plastic tube (cannula) with a wire running the length of its interior. A small portion of that wire is exposed at its distal end. The roof of the papilla is opened by passing high-frequency current through the needle knife, exposing the biliary or pancreatic orifices for selective cannulation.



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Intended Use

These devices are used for accessing the common bile duct when standard methods of cannulation have been exhausted.

Comparison to Predicate Device

The subject device and predicate device have the same intended use and different technological characteristics. None of the differences in technological characteristics raise different questions of safety and effectiveness. Furthermore, performance data from acceptable scientific testing methods provide evidence that the subject device is substantially equivalent to the predicate device.

Performance Data

Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing demonstrate that the Zimmon Needle Knife Papillotome meets the performance requirements to fulfill the intended use of the device.