DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2016

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

Re: K161203
Trade/Device Name: Soehendra Stent Retriever
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: April 27, 2016
Received: April 28, 2016

Dear Doris 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 yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161203

Device Name

Soehendra Stent Retriever

Indications for Use *(Describe)*

Used to remove stents from the biliary and pancreatic duct(s) while maintaining wire guide placement

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Name: Wilson-Cook Medical, Inc. / Cook Endoscopy
Address: 4900 Bethania Station Road
Winston-Salem, North Carolina 27105
Phone: (336) 744-0157 ext. 6293
Fax: (336) 201-5994
Contact: Doris A. Hawks, Global Regulatory Affairs Specialist
Date: April 27, 2016

Device Name

Trade Name: Soehendra Stent Retriever
Common Name: Stent Retriever
Classification Name: Catheter, Biliary, Diagnostic
21 CFR 876.5010, FGE, Class II

Predicate Device

Soehendra Stent Retriever, K903420, cleared October 22, 1990

Intended Use

Used to remove stents from the biliary and pancreatic duct(s) while maintaining wire guide placement.

Device Description

The modified Soehendra Stent Retriever (subject device) represents modifications made to the Soehendra Stent Retriever (predicate device) currently cleared to market via 510k: K903420 by Wilson-Cook Medical, Inc. The subject device consists of a knob-like handle and irrotational 7 Fr diameter cable available in 183 cm total length (168 cm working length, the portion of cable that fits inside endoscope channel) with a tapered threaded screw type distal tip configuration. The subject device is compatible with a .018” or .035” wire guide and is available with 5, 7, 8.5, 10 or 11.5 Fr tip diameters. The various tip diameters are offered in order to facilitate the removal of different size plastic biliary and pancreatic stents. The subject device is used by placing the cable through an endoscope over a prepositioned wire guide that has been passed through the stent lumen. The tip is screwed into the stent and the subject device and stent are

removed through the endoscope. If necessary, the wire guide can be left in place to allow placement of a new stent.

Substantial Equivalence

Minor design changes were made to the predicate Soehendra Stent Retriever cleared to market via K903420. These changes include: additional tip sizes, cable length measurement, reusable to disposable, single use device, compatibility with a .018 wire guide and the wire guide is no longer sold with device. The modified Soehendra Stent Retriever (subject device) is substantially equivalent to the predicate with respect to the intended use, key operating principles, materials and technological characteristics.

Performance Data

The Risk Analysis was completed to access the impact of modifications made to the cleared device using the Design Failure Modes, Effects and Criticality Analysis (DFMECA) method. Design verification and/or validation testing was performed as a result of this risk analysis assessment. Results from design validation and/or verification testing provide reasonable assurance that the modifications to the device do not raise any new questions of safety or effectiveness.

Conclusion

We believe risks associated with the modifications to the subject device have been adequately addressed through our Design Control Processes. We believe that the subject device is substantially equivalent to the predicate device in terms of intended use and performance characteristics (key operating principles, materials and technological characteristics).