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 18, 2017

Cook Incorporated
Erum B. Nasir
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K160567
Trade/Device Name: Barone Jejunostomy Catheter Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, PIO, OCY
Dated: April 20, 2017
Received: April 21, 2017

Dear Erum B. Nasir:

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)*
K160567

Device Name
Barone Jejunostomy Catheter Set

Indications for Use *(Describe)*
The Barone Jejunostomy Catheter Set is intended for patients older than 12 years old requiring jejunal feeding and delivery of medication. The device can be placed via a surgically open or laparoscopic technique.

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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510(k) SUMMARY

Barone Jejunostomy Catheter Set
21 CFR §807.92
Date Prepared: May 17, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Erum Nasir
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102607
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Barone Jejunostomy Catheter Set**
Common Name:	Tubes, Gastrointestinal (And Accessories)
Classification Name:	Gastrointestinal tube and accessories
Classification Regulations:	21 CFR §876.5980, Product Codes KNT, PIO 21 CFR §876.1500, Product Codes OCY
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Devices:

- Primary Predicate: Compat® Jejunostomy Feeding Tube Kit (K991668)
- Additional Predicate: Flexiflo Laparoscopic Jejunostomy Kit (K925102)

Device Description:

The Barone Jejunostomy Catheter Set is comprised of a jejunostomy catheter with a pre-loaded stiffening cannula, a Coons wire guide, a dilator, an enteral feeding adapter (funnel), two entry access needles, and a enteral transition connector. The Barone Jejunostomy Catheter is manufactured from polyether-urethane tubing. This catheter is a 10.2 Fr device with a proximal connector cap and a luer lock adapter, 6 distal sideports, a silicone suture wing, and a tapered distal tip; it has a length of 52 cm. The luer lock adapter is glued to the enteral feeding adapter (funnel) and thus is not functional for connecting to other devices. A 5.5 Fr polyethylene stiffener is also provided with the catheter and is matched for a transitional fit. The stiffener is designed with a pre-molded locking hub and a 0.035 inch diameter endhole.

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Indications for Use:

The Barone Jejunostomy Catheter Set is intended for patients greater than 12 years old requiring jejunal feeding and delivery of medication. The device can be placed via a surgically open or laparoscopic technique.

Comparison to Predicate Devices:

The Barone Jejunostomy Catheter Set and the predicate devices, the Compat® Jejunostomy Feeding Tube Kit (K991668) and the Flexiflo Laparoscopic Jejunostomy Kit (K925102), are substantially equivalent in that these devices have similar design and indications for use. Additionally, the proposed device has the same technological characteristics and methods of placement as those of the predicate devices. The differences between the subject device and the predicate devices include the materials, dimensions, number of sideports, retention mechanism, and included accessories.

Performance Data:

The following tests were performed to demonstrate that the proposed Barone Jejunostomy Catheter Set met the applicable design and performance requirements and support a determination of substantial equivalence.

- Tensile Testing (catheter, dilator, and enteral feeding adapter and enteral connector) – Testing demonstrated that the peak load value was greater than the predetermined acceptance criterion.
- Tensile Testing (catheter-matched stiffener, wire guide) – Testing demonstrated that the peak load value was greater than or equal to the predetermined acceptance criterion.
- Fracture Testing (wire guide) – Testing demonstrated that no signs of fracture were observed in the region of interest, according to the predetermined acceptance criterion.
- Corrosion Resistance (wire guide) – Testing demonstrated that there was no sign of corrosion that could affect the functional performance of the wire guide. The predetermined acceptance criterion was met.
- Resistance to Damage by Flex (wire guide) – Testing demonstrated that there were no signs of defects or damage, including flaking or material loss, when subjected to repeated flexing. The predetermined acceptance criterion was met.
- Liquid leakage (enteral feeding adapter and enteral connector) – Testing demonstrated that the connection did not leak. The predetermined acceptance criterion was met.

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- MRI Testing - MRI compatibility was assessed by evaluating magnetic field interactions (displacement force and torque), artifact, and RF-induced heating. The Barone Jejunostomy Catheter and the Enteral Feeding Adapter (funnel) are MR Safe according to ASTM F2503.
- Misconnection Testing - Testing shows that the connector should not provide a secure connection when forcefully assembled to any surface of the components of and should easily disengage from each connector of every other application category specified in ISO 80369-1:2010 or should a connection engage, then greater that 75% of the infusate should leak from the misconnection between the connector and the reference connector. Based on this testing, the potential for the misconnections in the following applications has been addressed in the labeling:
    - Intravascular or hypodermic applications (such as female luer lock fittings or male luer slip fittings).
    - Breathing systems and driving gases applications
- Torque Test (Catheter hub and enteral feeding adapter) – Testing demonstrated that the peak load value was greater than the predetermined acceptance criterion.
- Liquid leakage (Catheter and enteral feeding adapter) – Testing demonstrated that the connection did not leak. The predetermined acceptance criterion was met.
- Biocompatibility Testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous, systemic toxicity, subacute intraperitoneal toxicity, genotoxicity, and subcutaneous implant) shows that the devices are biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

Conclusion:

The results of these tests support a conclusion that the Barone Jejunostomy Catheter Set met the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate devices, the Compat® Jejunostomy Feeding Tube Kit (K991668) and the Flexiflo Laparoscopic Jejunostomy Kit (K925102).