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: K160509
Trade/Device Name: Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: April 12, 2017
Received: April 13, 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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)*
K160509

Device Name
Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube

Indications for Use *(Describe)*
The Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube is intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel in patients older than 12 years old.

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

Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube
21 CFR §876.5980
Date Prepared: 11 May 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Erum B. Nasir, MS
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:	Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube
Common Name:	Tubes, Gastrointestinal (And Accessories)
Classification Name:	Gastrointestinal tube and accessories
Regulation:	21 CFR §876.5980
Product Code	KNT

Predicate Device:

The Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube, subject of this submission, is substantially equivalent to the predicate device, the Wilson-Cook Nasal Jejunal Feeding Tubes and Nasal Jejunal Feeding Tube with Flaps, cleared under 510(k) number K043203.

Device Description:

The Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube consists of a 14 Fr polyether-urethane tube manufactured with a length of 153 cm. It has 5 sideports on the distal end for the purpose of delivering nutrition and/or medication. The shaft of the Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube includes 26-28 flaps cut into the tubing over the distal 40 cm segment of the device. These flaps provide a means for the catheter to be advanced by the natural peristaltic action of the gastrointestinal tract. The most distal flap is placed at approximately 2 cm from the distal tip of the catheter. Markings are placed along the shaft of the Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube in 5 cm increments (labeled at 10 cm increments). The proximal end of the shaft is attached to a red feeding adapter marked with the text “ENTERAL FEED/MED.” The Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube will be supplied sterile and is intended for one-time use.

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Intended Use:

The Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube is intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel in patients older than 12 years old.

Comparison to Predicate Device:

It has been demonstrated that the Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube is comparable to the predicate device. The Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube is identical in terms of intended use, principles of operation, and basic technological characteristics to the predicate device. The material of construction has been modified from polyvinyl chloride (PVC) of the predicate to polyether-urethane. An enteral feeding connector is also included in the device set. The safety and effectiveness of the modifications are supported by testing. A comparison between the predicate devices and the device subject of this submission is presented in Table 1.

Table 1 Substantial Equivalence Comparison

	PREDICATE DEVICE	SUBJECT DEVICE
	Wilson-Cook Nasal Jejunal Feeding Tubes and Nasal Jejunal Feeding Tube with Flaps (K043203)	**Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube**
Regulation Number	876.5980	876.5980
Product Code	KNT	KNT
Classification	Gastrointestinal tube and accessories	Gastrointestinal tube and accessories
Intended Use	Used for short-term enteral access for delivery of nutrition and/or medications to the small bowel.	Intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel in patients older than 12 years old.
Length	153 cm	Identical
Diameter	14 French	Identical
Mode of operation	Flaps allow catheter to be pulled into the small intestine by peristalsis	Identical
Catheter material	Polyvinyl chloride (PVC)	Polyether-Urethane
Barbed reduction connector material	Polypropylene	Identical
Tiger 2 adapter material	Polyvinyl chloride (PVC)	Identical
Feeding Connector	N/A	Cedic Enteral Distal End ENFit Transition Connector (K140581)

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	PREDICATE DEVICE	SUBJECT DEVICE
	Wilson-Cook Nasal Jejunal Feeding Tubes and Nasal Jejunal Feeding Tube with Flaps (K043203)	**Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube**
Sterilization, SAL	ETO, 10^{-6}	Identical
Packaging	Tyvek peel-open pouch	Identical

Test Data:

The following tests were performed to demonstrate that the Tiger 2™ Self-Advancing Nasal Jejunal Feeding Tube met applicable design and performance requirements and support a determination of substantial equivalence.

- Tensile Strength – Testing shows that the subject device should not break or crack during proper clinical use. The results showed that the predetermined acceptance criteria were met.
- Liquid Leakage Testing – Testing shows that the subject device should not leak during proper clinical use. The results showed that the predetermined acceptance criteria were met.
- 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. All test results are considered acceptable.
- Biocompatibility - Testing demonstrated that the subject device conforms to the biocompatibility requirements based on its intended use. Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, pyrogen, subchronic toxicity, subacute toxicity, and acute systemic toxicity demonstrated the biocompatibility of the subject devices. All test results are considered acceptable.

The results of these tests showed that the subject device 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 support a determination of substantially equivalence to the predicate device.