June 17, 2020

Wilson-Cook Medical, Inc
Tiffanny Thomas
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K201322
Trade/Device Name: Entuit Nasal Jejunal Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, KNT
Dated: May 15, 2020
Received: May 18, 2020

Dear Tiffanny Thomas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201332

Device Name

Entuit Nasal Jejunal Feeding Tube

Indications for Use *(Describe)*

This device is intended to provide short-term enteral access for delivery of nutrition and/or medications to small bowel. This device is indicated for adult use only.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Name: Wilson-Cook Medical, Inc. /Cook Endoscopy
Address: 4900 Bethania Station Road
Winston-Salem, North Carolina 27105
Phone: (336) 744-0157
Fax: (336) 201-5994

Contact; Theresa de Prat, Regulatory Affairs Specialist II

Tiffanny A. Thomas, Global Regulatory Affairs Specialist

Date: May 15, 2020

Trade Names: Entuit Nasal Jejunal Feeding Tube

Common Name: Nasal Jejunal Feeding Tube

Classification Name: Gastrointestinal Tube and Accessories 21 CFR §876.5980, KNT, PIF

Device: Class II

Predicate Device: Nasal Jejunal Feeding Tube Cleared May 11, 2005 K043203

Intended Use: This device is intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel. This device is indicated for adult use only.

Device Description:
The subject device is packaged with: a nasal feeding tube, a nasal transfer tube, a wire guide, and two feeding adapters. The single lumen nasal feeding tube is composed of radiopaque polyvinyl chloride with ink markings that are endoscopically visible and assist with tube placement. The nasal feeding tube is available in two diameters, 8 Fr and 10 Fr, with a length of 240 cm and 10 feeding ports. The nasal transfer tube has a diameter of 14 Fr, is composed of clear PVC and is 20 inches in length. The wire guide is stainless steel coated with polytetrafluoroethylene (PTFE) and is 250 cm in length. Two feeding adapters are provided; one as a friction fit version and one ENFit compatible.

Substantial Equivalence:
The main modification is adding a feeding adapter that has an ENFit connector and conforms to ISO 80369-3. The device subject to this 510k has the same intended use, methods of operation, and the fundamental technological characteristics as the cleared predicate.

Performance Data:
Performance testing consisting of non-clinical bench testing demonstrates the subject device meets the performance requirements to fulfill the intended use. This testing provides reasonable assurance that the subject device will function as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Summary of non-clinical testing:
The following non-clinical testing was conducted to demonstrate the performance of the subject device and confirms that the subject device performs as intended.

- ENFit Connector Testing per ISO 80369-3: 2016
- Design Verification of Feeding Adapters

Conclusion:
We believe that the subject device is substantially equivalent to the predicate device with respect to intended use, key operating principles, materials of construction, and technological characteristics. We consider the risks associated with the modifications to the subject device to have been adequately addressed through our Design Control Processes and do not affect the safety or effectiveness of the device.