January 20, 2022

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

Re: K213356
Trade/Device Name: Entuit PEG, Entuit PEGJ
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF, KNT
Dated: October 6, 2021
Received: October 12, 2021

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. In addition, we have determined that your device kit contains Lidocaine which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213356

Device Name
Entuit PEG
Entuit PEGJ

Indications for Use *(Describe)*

The Entuit PEG is intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition and/or medication to patients requiring nutritional support, and gastric decompression. This device is indicated for adult use only.

The Entuit PEGJ is intended for percutaneous endoscopic placement to provide enteral nutrition and/or medication to patients requiring nutritional support, and gastric decompression. 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Summary

Entuit PEG /Entuit PEGJ
Special 510(k) Premarket Notification
October 6, 2021

Applicant Information

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

Device Information

Trade Name:	Entuit PEG/ Entuit PEGJ
Regulation Number:	21 CFR 876.5980
Regulation Name:	Gastrointestinal tubes and accessories
Regulatory Class:	II
Product Code:	KNT, PIF

Predicate Device:
K183336 Entuit PEG / Entuit PEGJ cleared to market May 29, 2019

Device Description:
The Entuit PEG (subject device) includes a silicone enteral feeding tube (PEG tube) available in 24 Fr or 20 Fr, with site preparation components, introduction components, adapters, and connectors. The device is supplied sterile and is intended for single use in adults. Entuit PEGJ (subject device) includes a polyurethane enteral feeding tube (PEGJ tube) that is available in 12 Fr or 9 Fr. The Entuit PEGJ tube is for direct access to the jejunum. The 12 Fr PEGJ tube is designed to be inserted through the 24 Fr PEG tube and the 9 Fr PEGJ tube is designed to be inserted through the 20 Fr PEG tube such that the distal end extends into the jejunum and the proximal end extends out of the existing PEG tube.

There are several feeding adapters for use with the PEG and PEGJ tubes. The PEG kit has one feeding adapter that is ENFit compatible and two feeding adapters that are compatible with Christmas tree/slip tip giving sets and syringes (Non-ENFit). The PEGJ tubes are also available with either ENFit compatible or Christmas tree compatible feeding adapters (Non-ENFit).

The Entuit PEG is provided as a kit to facilitate either push or pull techniques of placement. In addition, the Entuit PEG kits are available in standard, safety, and international versions. The Entuit PEGJ is sold as a separate kit and available in standard versions.

Intended Use:
The Entuit PEG is intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition and/or medication to patients requiring nutritional support, and gastric decompression. This device is indicated for adult use only.

The Entuit PEGJ is intended for percutaneous endoscopic placement to provide enteral nutrition and/or medication to patients requiring nutritional support, and gastric decompression. This device is indicated for adult use only.

Comparison to Predicate Device:
The subject Entuit PEG and Entuit PEGJ are substantially equivalent to the predicate devices, K183336 Entuit PEG / Entuit PEGJ cleared to market May 29, 2019, with respect to the indications for use, methods of placement, designs, and fundamental technological characteristics. The minor differences between the subject devices and the predicate devices include design and material changes: to the feeding tubes and introducer components, ENFit feeding adapters, and packaging.

Summary of Non-Clinical Testing:
The following non-clinical testing was conducted to demonstrate the performance of the subject devices and confirmed that the subject devices perform as intended.

- Functional Validation
- Tensile Testing
- Leak testing
- Shelf-Life Testing
- Enteral Connector Misconnection
- ENFit Performance Testing
- Feeding Adapters Tensile Testing
- Biocompatibility Testing
- Flow Rate
- Radiopacity
- Bolster Separation Forces
- Ink marking durability
- Force required to Pull the Bolster Through the Stoma Testing

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1 "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process."

Conclusions:
We believe that the subject device is substantially equivalent to the predicate device in terms of intended use, key operating principles, materials, 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 safety or effectiveness of the device.