December 19, 2019

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

Re: K190829
Trade/Device Name: Gastrointestinal Injection Needles (VIN, LDVI, DVI and MHI)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: November 4, 2019
Received: November 5, 2019

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. 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,

for
Shani P. Haugen, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190829

Device Name
Gastrointestinal Injection Needles (VIN, LDVI, DVI and MHI)

Indications for Use *(Describe)*

This device is used for endoscopic injection into gastrointestinal mucosa. The intended population is 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

Submission Information

Type: Traditional 510(k) Premarket Notification
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: Tiffanny A. Thomas, Global Regulatory Affairs Specialist
Therese de Prat, Regulatory Affairs Specialist II

Date: December 11, 2019

Trade or Proprietary Name: Gastrointestinal Injection Needles (VIN, LDVI, DVI and MHI)
Common/Usual Name: Endoscopic Injection Needle, Gastroenterology-Urology
Classification Name: Endoscope and accessories
Device Classification: Class II
Regulation Number: 21 CFR 876.1500
Review Panel: Gastroenterology-Urology

Procode: FBK
Predicate Device: Wilson-Cook Variable Length GI Injection Needle, K941305/A, cleared June 2, 1994

Intended Use:
This device is used for endoscopic injection into gastrointestinal mucosa. The intended population is adult use only.

Device Description:
The Gastrointestinal Injection Needles (subject devices) are sterile, single use devices that consist of a needle on an inner catheter fitted inside an outer catheter sheath featuring a luer slip/adjustment wheel handle with either a plastic or metal hub used as an injection port at the proximal end of the device. The devices are compatible with endoscopes with a minimum accessory channel of 2.0 mm or 2.8 mm. The Gastrointestinal Injection Needles have catheters which ranges in length from 195 to 315 cm, outer diameters of 5.4 FR and 6.9 FR, and needle gauges of 21, 23 and 25. Some configurations of the Gastrointestinal Injection Needles include ink marks at the distal end of the device to aid endoscopic visualization.

Substantial Equivalence:
The Gastrointestinal Injection Needles (subject device) is substantially equivalent to the predicate device with respect to the intended use, operating principle and the technological characteristics.
Minor changes were made from predicate Wilson-Cook Variable Length GI Injection Needle cleared to market via K941305/A. These changes include catheter dimensions, material changes and needle configurations. The modifications do not result in a change of intended us or indications.

Performance Data:
Performance testing consisting of non-clinical bench testing demonstrates that the Gastrointestinal Injection Needles meet the performance requirements to fulfill the intended use of the device. 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.

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

- Functional Testing
- Tensile Strength Testing
- Needle Verification and Validation Testing
- Shelf Life Testing
- Packaging Validation

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part I: Evaluation and testing within a risk management process" and per ISO 10993-1:2009, Biological evaluation of medical devices-Evaluation and testing within risk management process.

Conclusion:
We believe that the subject devices are 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.