April 26, 2022

Wilson Cook Medical
Paul Meyer, Ph.D.
Regulatory Scientist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K213483
Trade/Device Name: SnapLoc Wire Lock
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: March 10, 2022
Received: March 22, 2022

Dear Paul Meyer:

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
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)*
K213483

Device Name
SnapLoc Wire Lock

Indications for Use *(Describe)*
This device is an accessory to be used with endoscopic biliary and pancreatic devices to lock the wire guide(s) in place and to prevent reflux of bodily fluids during ERCP

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.

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510(k) Summary

SnapLoc Wire Lock
21 CFR §876.1500
Date Prepared: December 17, 2021

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Wilson Cook Medical, Inc.
Applicant Address:	4900 Bethania Station Road Winston-Salem NC 27105
Contact:	Paul Meyer
Email:	paul.meyer@cookmedical.com
Contact Phone Number:	(812) 335-3575 x105299
Contact Fax number:	(812) 332-0281

Device Information:

Trade Name:	**SnapLoc Wire Lock**
Device Common Name:	Endoscope and accessories
Classification Regulation:	21 CFR §876.1500, Product Code ODC
Classification Panel:	Gastroenterology/Urology

Predicate Device:

The SnapLoc Wire Lock is substantially equivalent to the following device: Fusion Wire Guide Locking Device (K040137, Wilson Cook Medical).

Device Description:

The SnapLoc Wire Lock device is an accessory that is clipped onto the outside of a Duodenoscope during Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedures. Its purpose is to help control the wire guides during a procedure, to enable ERCP devices (catheters, baskets, balloons, stents, etc) to pass through the device and to prevent the backflow of bodily fluids during procedures. The SnapLoc wire lock contains features to aid in wire control. The wire is locked into place by simply sliding the wire into one of the locking notches located on the left and right sides of the wire lock. The wire is unlocked by lifting the wire out of the wire locking notch. For control, the proximal end of the wire can be secured by inserting it into one of the docking channels. A silicone seal located between the molded components helps reduce leakage from the duodenoscope. For ease of connection, the wire lock attaches to the duodenoscope by sliding laterally onto the port until secure. The SnapLoc will be sold in three sizes to be compatible with the most commonly used endoscopes from Olympus, Fuji, and Pentax.

Indications for Use:

This device is an accessory to be used with endoscopic biliary and pancreatic devices to lock the wire guide(s) in place and to prevent reflux of bodily fluids during ERCP

Substantial Equivalence:

Nearly all technological characteristics between the subject and predicate device are similar, however, there are some minor differences in indications for use, product code, seal material, and shelf-life as described in the following table.

	PREDICATE DEVICE	SUBJECT DEVICE
	Fusion Wire Guide Locking Device (K040137)	**SnapLoc Wire Lock**
Product Code	OCY	ODC
Indications for Use	This device is an accessory to be used with endoscopic biliary devices to lock the wire guide(s) in place during ERCP procedures.	This device is an accessory to be used with endoscopic biliary and pancreatic devices to lock the wire guide(s) in place and to prevent reflux of bodily fluids during ERCP
Shelf Life	3 years	1 year
Seal Material	Chlorinated synthetic polyisoprene and polyurethane foam	Silicone

Indications for Use Comparison:

The predicate, Fusion Wire Lock, is intended to be used with endoscopic biliary devices to lock the wire guide(s) in place during ERCP procedures. The SnapLoc device has the same indication with the addition indications of use with pancreatic devices and the ability to prevent fluid reflux during the procedure. ERCP procedures enable access to the common bile duct which includes pancreatic and biliary access and therapies (e.g. stent placement, stone removal, etc). During the course of ERCP treatments, a physician often has to place a pancreatic stent in the patient for the prevention of post-ERCP pancreatitis. This determination is only made during the procedure, and so both the Fusion Wire Guide Locking Device and the SnapLoc Wire Lock support both biliary and pancreatic devices during ERCP, despite pancreatic devices not being explicitly stated in the predicate indications for use. The ability to prevent reflux is also a feature of the predicate, Fusion Wire Lock, however it is not captured explicitly in the indications for use. Therefore, these differences do not constitute a new intended use.

Technological Characteristics:

Performance testing was conducted to demonstrate that the SnapLoc Wire Guide Lock meets the design input requirements identified based on the intended use of the device, and where

appropriate, applicable standards. Where applicable, each test was performed on each variant of the SnapLoc device based on endoscope compatibility (Olympus, Fuji, Pentax).

Verification testing was conducted on final, finished devices to demonstrate the subject devices meet their design requirements. The following tests were performed to demonstrate conformance to their design input requirements as well as substantial equivalence to the predicate Fusion Wire Locking Device:

- Force to Connect to Duodenoscope
- Leakage Rate At Scope Seal
- Force to Advance Device Through Wirelock
- Ability to Lock Wireguide
- Leakage Rate at Accessory Seal
- Force to Remove Catheter During Short Wire Exchange
- Translation Distance of Wire in Locked Position
- Force to Detach from Duodenoscope
- Joint Strength during Short Wire Exchange/Stent Use

Applicable testing was conducted on representative devices at time zero and accelerated aging to a real-time equivalency of one year where appropriate to support the subject SnapLoc Wire Locks for their labeled shelf-life. Material assessments following accelerated aging demonstrated no significant change in the polycarbonate material composing the majority of the device, therefore, verification endpoints related to this material (e.g. joint strength) evaluated at time zero are also representative of aged devices. Successful functional testing of the subject SmapLoc Wire Lock supports a determination of substantial equivalence to the predicate device.

Non-clinical testing on the SnapLoc Wire Lock on all critical performance characteristics (compatibility with scopes, ability to lock wires in place, leakage, etc.) and biocompatibility demonstrates that the subject device does not raise any new questions of safety or effectiveness compared to the predicate, Fusion Wire Lock. A full comparison between the subject and predicate devices is presented in the Substantial Equivalence section of this submission.