August 25, 2021

Wilson-Cook Medical Inc.
Scottie Fariole
Regulatory Science Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K212323
Trade/Device Name: Instinct Plus Endoscopic Clipping Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: July 23, 2021
Received: July 26, 2021

Dear Scottie Fariole:

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 control's 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.

Submission Number *(if known)*

K212323

Device Name

Instinct Plus Endoscopic Clipping Device

Indications for Use *(Describe)*

This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of:
1. Endoscopic marking,
2. Hemostasis for
• Mucosal/submucosal defects less than 3 cm,
• Bleeding ulcers,
• Arteries less than 2 mm,
• Polyps less than 1.5 cm in diameter,
• Diverticula in the colon, and
• Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection,
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively,
5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.

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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WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

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:	Scottie Fariole, Regulatory Science Specialist
Date:	August 25, 2021

Device Name:	Instinct Plus Endoscopic Clipping Device
Common Name:	Hemostatic Metal Clip For The Gi Tract or Endoscopic Clipping Device
Classification Name:	Hemorrhoidal Ligator (21 CFR 876.4400, Product Code PKL)
Product Code Name:	Hemostatic Metal Clip For The Gi Tract
Regulatory Class:	Class II Device

Predicate Device:	Instinct Plus Endoscopic Clipping Device (K192697)

Description of the Device:

The Instinct Plus Endoscopic Clipping Device is a sterile, single use metallic clip used for tissue approximation and hemostasis in the gastrointestinal tract. The metallic clip is 14.4 mm long and has an opening span of 16 mm. The clip is preloaded on a 230 cm long introducer comprised of a coated coil spring, drive wire and deployment handle. The clip may be deployed to the site of interest using a straight viewing flexible endoscope with a minimum accessory channel of 2.8 mm, or side viewing flexible endoscope with a minimum accessory channel of 4.2 mm. The clip can be rotated for positioning by rotating the handle of the introducer and may be reopened and closed up to five times prior to deployment. The Instinct Plus Endoscopic Clipping Device is supplied sterilized by ethylene oxide gas in a peel-open package and intended for one-time use. The product is packaged with three-year shelf life.

Cook Endoscopy – Special 510(k)
Instinct Plus Endoscopic Clipping Device

Intended Use:

This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of:
1. Endoscopic marking,
2. Hemostasis for
   - Mucosal/submucosal defects less than 3 cm,
   - Bleeding ulcers,
   - Arteries less than 2 mm,
   - Polyps less than 1.5 cm in diameter,
   - Diverticula in the colon, and
   - Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection,
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively,
5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.

Technological Characteristics:

The subject Instinct Plus Endoscopic Clipping Device is substantially equivalent to the referenced Instinct Plus Endoscopic Clipping Device (K192697) with respect to Indications for Use, Principles of Operation and overall device design, dimensions, shape and material. The change that is the subject of this 510(k) is to tighten the dimensional specification and tolerance on the proximal end of the catheter attach component of the introducer. The purpose of the change is to improve deployment consistency and address events related to inability to deploy clip observed in clinical use. A comparison of the key feature of the subject device and predicate device is included in the Substantial Equivalence Comparison table.

Summary Substantial Equivalence Comparison Table:

Parameter	Instinct Plus Endoscopic Clipping Device (Subject Device)	Instinct Plus Endoscopic Clipping Device (K192697)	Comparison
Indications for Use	This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of 1. Endoscopic marking, 2. Hemostasis for • Mucosal/submucosal defects less than 3 cm • Bleeding ulcers,	This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of 1. Endoscopic marking, 2. Hemostasis for • Mucosal/submucosal defects less than 3 cm • Bleeding ulcers,	Identical

Cook Endoscopy – Special 510(k)
Instinct Plus Endoscopic Clipping Device

Parameter	Instinct Plus Endoscopic Clipping Device (Subject Device)	Instinct Plus Endoscopic Clipping Device (K192697)	Comparison
	• Arteries less than 2 mm, • Polyps less than 1.5 cm in diameter, • Diverticula in the colon, and • Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection, 3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel, 4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively, 5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.	• Arteries less than 2 mm, • Polyps less than 1.5 cm in diameter, • Diverticula in the colon, and • Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection, 3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel, 4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively, 5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.	
Packaging	Pouch	Pouch	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Shelf Life	3 Years	1 Year	Subject device is supported for three-year shelf life based on the same method described in the previous 510(k). Change in Shelf Life was not the result of device modification, nor did the change impact shelf life.
Configuration	Delivery system and clip	Delivery system and clip	Identical
MR Conditional	Yes	Yes	Identical
Clip			
Number of Prongs	2	2	Identical

Cook Endoscopy – Special 510(k)
Instinct Plus Endoscopic Clipping Device

Parameter	Instinct Plus Endoscopic Clipping Device (Subject Device)	Instinct Plus Endoscopic Clipping Device (K192697)	Comparison
Jaw Width	16 mm	16 mm	Identical
Clip Geometry	Cylindrical housing, rounded arms with serrated tip	Cylindrical housing, rounded arms with serrated tip	Identical
Number of Open-Close Cycles Prior to Deployment	5	5	Identical
Handle Controlled Clip Rotation	Yes	Yes	Identical
Introducer			
Working Length	230 cm	230 cm	Identical
Introducer Diameter (nominal)	7 Fr	7 Fr	Identical
Minimum Working Channel of Endoscope	2.8 mm for forward viewing endoscope, and 4.2 mm for side viewing endoscope	2.8 mm for forward viewing endoscope, and 4.2 mm for side viewing endoscope	Identical

Non-Clinical and/or Clinical Tests Summary and Conclusions:	Baseline testing consisting of non-clinical bench testing demonstrates that the Instinct Plus Endoscopic Clipping Device enabled consistent deployment of the clip to fulfill the intended use of the device. Validation testing was repeated to deploy devices without tissue to simulate worst case. Validation testing was also repeated utilizing process data to confirm the Strength of Distal Coil Cath Tabs met acceptance criteria. Testing passed demonstrating the device is substantially equivalent to the currently cleared predicate device.