March 5, 2020

Cook Endoscopy
Karthik Pillai
Regulatory Scientist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K192697
Trade/Device Name: Instinct Plus Endoscopic Clipping Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated: January 28, 2020
Received: January 29, 2020

Dear Karthik Pillai:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192697

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 20mm 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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510(k) SUMMARY

Instinct Plus Endoscopic Clipping Device
21 CFR §876.4400
Date Prepared: 4 March 2020

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Endoscopy (Wilson-Cook Medical, Inc)
Applicant Address:	4900 Bethania Station Road Winston-Salem, NC 27105
Primary Contact:	Karthik Pillai, Ph.D., RAC
Contact Phone Number	812-335-3575 x104929

Device Information:

Device Name:	**Instinct Plus Endoscopic Clipping Device**
Common Name:	Endoscopic Clipping Device
Classification Number:	21 CFR §876.4400
Classification Name:	Hemorrhoidal Ligator
Product Code:	PKL
Product Code Name:	Hemostatic Metal Clip for the Gi Tract
Regulatory Class:	II

Predicate Devices:

- K151802 Resolution™ 360 Clip (primary)
- K132809 Instinct Endoscopic Hemoclip (secondary)

Device Description:

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 one-year shelf life.

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 20mm 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 Instinct Plus Endoscopic Clipping Device has identical or similar technological characteristics, and mode of operation compared to the predicate devices. The subject device and the predicate devices have the same Intended Use and similar Indications for Use. The comparison of technological characteristics is provided in table 1. The primary difference between the subject device and the predicates are materials, dimensions and design elements. These differences do not affect device performance as demonstrated by biological and functional testing of the subject device.

Table 1. Comparison between predicates and the subject device

Device Characteristics	Primary Predicate Resolution™ 360 Clip	Secondary Predicate Instinct Endoscopic Hemoclip	Subject Device Instinct Plus Endoscopic Clipping Device	Comparison
510(k)	K151802	K132809	Subject of this submission	N/A
Manufacturer	Boston Scientific Corporation	Wilson-Cook Medical, Inc./Cook Endoscopy	Wilson-Cook Medical, Inc./Cook Endoscopy	Same manufacturer as Secondary Predicate
Device Class	II	II	II	Identical
Indications for Use	The Resolution™ 360 Clip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of: 1. Endoscopic marking 2. Hemostasis for: • Mucosal/sub-mucosal defects < 3 cm • Bleeding ulcers • Arteries < 2 mm • Polyps < 1.5 cm in diameter • Diverticula in the colon • 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; and Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus 4. As a supplemental closure method of luminal perforations < 20 mm that can be treated conservatively.	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 in the upper GI tract, • Bleeding ulcers, • Arteries less than 2 mm, and • Polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract luminal perforations.	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 20mm 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	Same indications for use as primary predicate and added indications compared to the secondary predicate. The indications are identical to primary predicate and do not raise additional questions of safety and effectiveness (S&E).

Device Characteristics	Primary Predicate Resolution™ 360 Clip	Secondary Predicate Instinct Endoscopic Hemoclip	Subject Device Instinct Plus Endoscopic Clipping Device	Comparison
			fistulas, leaks, perforations, or disunion.	
Packaging	Pouch	Pouch	Pouch	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical
Shelf Life	3 years	3 Years	1 year	The subject device is supported for a shelf life of one year.
Configuration	Delivery system and clip	Delivery system and clip	Delivery system and clip	Identical
MR Conditional	Yes	Yes	Yes	Identical
Clip				
Number of Prongs	2	2	2	Identical
Jaw Width	11 mm	16 mm	16 mm	The jaw width of the open clip is larger than primary predicate, and identical to the secondary predicate. This difference does not affect S&E.
Clip Geometry	Cylindrical housing, rounded arms with serrated tip	Cylindrical housing, flat arms with serrated tip	Cylindrical housing, rounded arms with serrated tip	Clip geometry is identical to the primary predicate, but slightly different than the secondary predicate. No effect on S&E.
Number of Open-Close Cycles Prior to Deployment	5	5	5	Identical
Handle Controlled Clip Rotation	Yes	Yes	Yes	Identical
Material	Stainless steel, Cobalt chrome and Styrene	Stainless-steel and Nitinol	Stainless-steel, Delrin, and Nitinol	Difference in material evaluated by biological and performance testing and shown not to affect S&E.
Introducer				
Working length	155, 235 cm	230 cm	230 cm	Subject device only sold in one device length which is similar to the larger size of primary predicate and identical in length to secondary predicate.

Device Characteristics	Primary Predicate Resolution™ 360 Clip	Secondary Predicate Instinct Endoscopic Hemoclip	Subject Device Instinct Plus Endoscopic Clipping Device	Comparison
Introducer Diameter (nominal)	7 Fr	7 Fr	7 Fr	Identical
Minimum Working Channel of Endoscope	2.8 mm	2.8 mm	2.8 mm for forward viewing endoscope, and 4.2 mm for side-viewing endoscope	The subject device has been evaluated for compatibility with side-viewing endoscopes and found to be compatible with scopes with at least a 4.2 mm working-channel.
Material: Introducer Coil Spring	Stainless steel	Stainless Steel, Polyether block polyamide copolymer	Stainless steel, Polyether block polyamide copolymer	Difference in material evaluated by biological testing and performance testing and shown not to affect S&E.
Drive Wire	Stainless steel	Nitinol	Nitinol, polyarylamide	
Material: Handle	Thermoplastic elastomers, polyethylene and polyester	Polystyrene, polypropylene and polycarbonate	Polystyrene, polypropylene and polycarbonate	

Performance Data:

Performance testing was conducted to meet the following design input requirements:

1. Sterility
2. Packaging
3. Biocompatibility
4. Advance device into the GI tract through a compatible endoscope
5. Position and approximate target site
6. Deploy clip onto targeted GI tissue
7. Removal of device from the endoscope
8. Force of clip retention at tissue
9. Force of clip compression at tissue
10. Strength of clip assembly
11. Strength of clip housing
12. MRI Testing

13. Corrosion testing
14. Force to deploy clip on tissue handle

15. Strength of Introducer Coil Cath
16. Strength of Handle and Drivewire

Conclusion:

The results of these tests provide reasonable assurance that the Instinct Plus Endoscopic Clipping Device met the design input requirements based on the intended use. The subject device does not raise new questions of safety or effectiveness as compared to the predicate devices.