December 15, 2020

Apollo Endosurgery, Inc.
Natalie Allen
Regulatory Affairs Specialist
1120 S. Capital of Texas Hwy
Austin, Texas 78749

Re: K201808
Trade/Device Name: X-Tack Endoscopic HeliX Tacking System
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL, OCW
Dated: November 5, 2020
Received: November 6, 2020

Dear Natalie Allen:

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,

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)*
K201808

Device Name
X-Tack Endoscopic HeliX Tacking System

Indications for Use *(Describe)*
The X-Tack™ Endoscopic HeliX Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). X-Tack is not intended for hemostasis of acute bleeding ulcers.

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

Owner's Name & Address:

Apollo Endosurgery
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Building 1, Suite 300
Austin, TX 78746

Contact Person:

David M. Hooper, PhD
Vice President, Quality and Regulatory Affairs
Phone: (512) 279-5100
Email : david.hooper@apolloendo.com

Date: December 10, 2020

Trade Name: X-Tack™ Endoscopic HeliX Tacking System

Common Name: Endoscopic Tissue Approximation Device

Product Code: PKL, OCW

Classification: Class II (21 CFR 876.4400)

Classification Name Hemorrhoidal Ligator

Predicate Devices: K151802 – Resolution™ 360 Clip

Device Description

X-Tack™ Endoscopic HeliX Tacking System

The X-Tack™ Endoscopic HeliX Tacking System is a sterile, single-use device that enables the user to approximate soft tissue in the gastrointestinal (GI) tract using helix tacks and a 3-0 suture through a 2.8 mm or larger working channel of an endoscope (e.g. gastroscope or colonoscope).

OverStitch Suture Cinch

The Overstitch Suture Cinch device is comprised of thermoplastic and stainless steel materials and includes an implantable PEEK Cinch component designed to secure and cut the suture once tissue approximation is complete. It is the final step of the X-Tack procedure. The device functions by squeezing the handle and deploying the PEEK components, which form a press-fit onto the tail end of the suture to maintain suture position *in situ*.

Indications for Use: The X-Tack™ Endoscopic HeliX Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). X-Tack is not intended for hemostasis of acute bleeding ulcers

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Technological Characteristics:

The X-Tack™ Endoscopic Helix Tacking System shares technological characteristics similar to the predicate device. These characteristics include:

- Equivalent intended use
- Endoscopic delivery of closure device
- Manufactured from materials commonly utlilized for implant devices used in the gastrointestinal (GI) tract
- Similar design concept in that a force is delivered by the implant to approximate soft tissue.
- Sterilized using an ethylene oxide (EO) process
- Equivalent performance in a randomized, controlled animal study, specifically evaluating the closure and healing of defects over the course of one month, as evaluated through direct visualization and histological analysis.

Basis of Substantial Equivalence:

Non-clinical testing was performed to verify anchor retention, suture tensile strength, and endoscope compatbilitity. Testing was performed to validate usability and human factors, packaging, shelf-life and the ability of the device to withstand distribution forces. The sterilization cycle and biocompatibility of the device were validated per recognized ISO standards. MR testing was performed to establish the conditions underwich the device could be safety scanned, as well as the heating and artefact that could be expected during MRI scanning. MR testing included scanning to determine induced forces, followed by laboratory tests to verify safety under maximum scan conditions.

A randomized study involving 4 pigs and 40 defects (created in the stomach and colon), was done to compare the closure rates and healing between X-Tack and the predicate. That study demonstrated that the closure rates associated with X-Tack were equivalent to the predicate and that X-Tack enabled larger defects to be closed. Histological analysis of defects showed both devices resulted in healing of defects.

Based on the non-clinical and animal testing, the device is as safe and effective, and performs as well or better than the legally marketed predicate device.

Summary Table of Equivalence

	X-Tack	**Predicate**
Principle of Operation	• Device is inserted into an endosope and deployed at target site. • Helix tacks are deployed independently around the defect. • Implanted construct closes the defect through metallic anchors and suture tension.	• Device is inserted into an endoscope and deployed at target site. • Clips are deployed independently around the defect. • Implanted construct consists of metallic arms and spring tension.

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Endoscope compatability	Scopes with a 2.8mm working channel.	Scopes with a 2.8mm working channel.
Working length	Gastric: 155 cm Colon: 235 cm	Gastric: 160 cm Colonic: 235 cm
Respositionable prior to deployment	Yes	Yes
Physician control over placement and final locking	Yes	Yes
Expected implant duration.	Approximately 1 month or less, then implant is passed in stool.	Approximately 1 month or less, then implant is passed in stool.
Clip opening width	Not applicable. Device uses independent tacks, suture and cinch and is not limited by a clip opening dimension.	11 mm
Closure efficacy in animal study	100% closure at 4 weeks. Histologic evaluations of closure were consistent with wound healing.	100% closure at 4 weeks. Histologic evaluations of closure were consistent with wound healing.
Sterilization Method	EO	EO
Usage	Single-use	Single-use
Implanted Materials	Helix Tack: 316L Stainless Steel Cinch: VESTAKEEP i4 (PEEK) Suture: Polyproylene USP 3-0 Polypropylene Copper Phthalocyannine Blue (Below 0.5WT%) in accordance with 21 CFR 74, 3045	Capsule: 304 Stainless Steel Arms: 17-7 PH SS Tension breaker: Luran 968R (polystyrene) Yoke: F75 Cobalt Chrome
Biocompatibility	Tested per ISO 19993.	Tested per ISO 19993.
MR Compatibility	MR Conditional with 1.5 and 3 T MR scanners with spatial field gradient of 2500 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning.	MR Conditional with 1.5 and 3 T MR scanners with spatial field gradient of 2500 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning.