March 2, 2021

Apollo Endosurgery Inc.
David Hooper
VP Quality and Regulatory
1120 South Capital of Texas Hwy., Suite 300
Austin, Texas 78746

Re: K210266
Trade/Device Name: OverStitch Sx Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: January 28, 2021
Received: February 1, 2021

Dear David Hooper:

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 Cindy Chowdhury, Ph.D., MBA
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K210266

Device Name
OverStitch Sx Endoscopic Suturing System

Indications for Use *(Describe)*
The OverStitch Sx Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

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
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Contact Person:

David M. Hooper, PhD
VP Quality and Regulatory
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Submission Compiled By:

Lisa Peterson
Kaedon Consulting, LLC
lpeterson@kaedonconsulting.com

Date:

March 2, 2021

Trade Name:

OverStitch™ Sx Endoscopic Suturing System

Common Name:

Endoscopic Tissue Approximation Device

Product Code:

OCW

Classification:

Class II (21 CFR 876.1500)

Classification Name

Endoscope and Accessories

Predicate Devices:

K181141 – OverStitch™ Sx Endoscopic Suturing System

Device Description

The OverStitch™ Sx Endoscopic Suturing System and accessories are intended for endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract utilizing a single-channel endoscope. The system is comprised of the Needle Driver Assembly and Anchor Exchange Device (collectively referred to as ESS), and accessories such as the Tissue Helix, Suture Cinch and Suture-Anchor Assembly devices. All devices are sterile packaged and designed for single use and are manufactured from various thermoplastic, silicone, stainless steel and other medical grade materials.

The OverStitch Sx ESS is designed for compatibility with single channel endoscopes. The ESS is mounted onto the endoscope using thermoplastic polyurethane straps for the endcap assembly. The external catheter sheath has two working channels through which the Anchor Exchange and OverStitch accessories can operate, independent of the endoscope channel.

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The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the proprietary Suture-Anchor Assembly with the Anchor Exchange to perform stitching operations.

Indications for Use:

The OverStitch Sx Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

Technological Characteristics:

Modifications to design and materials as compared to the predicate device cleared via K181141 are as follows:

- Material Change: Endcap material changed to support change from machined component to plastic injection molded component. Adhesive changed for endcap glue joints to improve manufacturability.
- Dimensional Change: Minor geometry adjustments made to support injection molding requirements.
- Biopsy Valve components provided and pre-installed on Handle

Non-Clinical Performance Data:

Appropriate product testing was performed on the subject device to evaluate conformance to product specifications and equivalence to the predicate designs. Verification and validation for the proposed system of devices was conducted in accordance with written protocols, previously applied to the predicate device. All devices were evaluated to their individual functional and reliability requirements, as well as system compatibility.

Performance Testing

Bench testing included suture drag testing, tensile testing, endoscope compatibility, reliability and bond strength.

Functional Testing

An ex vivo model was utilized under the same test methods as the predicate to evaluate the device function and intended use.

Packaging Integrity

Packaging Integrity was confirmed by repeating testing in accordance with ASTM F2096-11, ASTM F1980-16, ASTM D4169-16 and ASTM F88/F88M-15.

Acceptance criteria were met in each of the studies listed above. The results confirmed equivalency between the subject and predicate devices, and that no new issues of safety or efficacy were raised.

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Biocompatibility: Biocompatibility testing and toxicological assessments were performed on subject OverStitch devices in accordance with their risk category requirements, as defined in ISO 10933-1. Testing included cytotoxicity, irritation and skin sensitization, systemic toxicity, and material mediated pyrogenicity.

Clinical Performance Data: Clinical testing was not required to demonstrate substantial equivalence.

Basis of Substantial Equivalence: Based on a comparison of indications for use and technological characteristics, the proposed devices have demonstrated substantial equivalence to their predicates.

Table 1 Summary Table of Equivalence

	Predicate OverStitch Sx ESS (K181141)	**Modified Sx ESS Device**
Indications for Use	The OverStitch Sx Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.	Same
Endoscope Compatibility	Compatible with single channel endoscopes having an outer diameter range of 8.8 to 9.8 mm	Same
Working Length	Maximum working length of 110 cm	Same
Sterilization Method	EO	Same
Shelf Life	3 years	Same
Usage	Single-use	Same
Biocompatibility	Tested per ISO 19993.	Same
MR Compatibility	Safe with 1.5 and 3 T MR scanners with spatial field gradient of 2000 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning	Same