November 15, 2017

Apollo Endosurgery
Ms. Maritza Ward
Manager, Regulatory Affairs
1120 S. Capital of Texas Hwy.
Building 1, Suite 300
Austin, Texas 78746

Re: K171886
Trade/Device Name: OverStitch Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: HCF
Dated: October 12, 2017
Received: October 16, 2017

Dear Ms. Ward:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K171886

Device Name
Overstitch™ Endoscopic Suturing System

Indications for Use *(Describe)*
The OverStitch™ 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 1120 S. Capital of Texas Hwy. Building 1, Suite 300 Austin, TX 78746
Contact Person:	Maritza Ward Manager, Regulatory Affairs Phone: (512)-279-5114 Email : Maritza.Ward@apolloendo.com
Date:	November 9, 2017
Trade Name:	OverStitch™ Endoscopic Suturing System
Common Name:	Endoscopic Tissue Approximation Device
Product Code:	HCF
Classification:	Class II (21 CFR 876.1500)
Classification Name	Endoscope and Accessories
Predicate Devices:	K081853 – OverStitch™ Endoscopic Suturing System
Device Description	The OverStitch™ Endoscopic Suturing System and accessories are intended for endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract utilizing either a dual channel or 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 and Suture Cinch devices. All devices are sterile packaged and designed for single use and are manufactured from various thermoplastic, silicone and stainless steel materials. OverStitch ESS The OverStitch ESS is designed for compatibility with dual channel endoscopes. The endcap of the Needle Driver Assembly attaches to the distal end of the endoscope, and the handle attaches to the proximal end. The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the proprietary suture assembly with the Anchor Exchange to perform stitching operations. OverStitch Sx ESS

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The OverStitch Sx ESS is designed for compatibility with single channel endoscopes. The ESS is mounted onto the endoscope using silicone straps distributed along the length of the catheter and 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. 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.

OverStitch Tissue Helix

The OverStitch Helix is an optional device that is designed to acquire tissue by rotating the device handle into targeted area until tissue is gathered into the exposed helix coil. The acquired tissue is then pull into proximity of the needle body to complete the stitching operation.

OverStitch Suture-Anchor Assembly

The OverStitch Suture-Anchor Assembly is comprised of a 510(k) cleared suture product, manufactured from either polydioxanone or polypropylene materials attached to an implantable anchor manufactured from cobalt chrome and stainless steel. The Anchor component is intended to function with the OverStitch ESS device to perform stitching operations and serves as an anchor to secure suture placement, once released from the ESS.

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 the placement of suture as a final step of an OverStitch procedure. The device functions by squeezing the handle and deploying the PEEK components that press-fit onto the tail end of the suture to maintain suture position in situ.

Indications for Use:

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

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Technological Characteristics:

NEEDLE DRIVER ASSEMBLY	Gen 0 Needle Driver Assembly	Gen 2 Needle Driver Assembly	Sx Needle Driver Assembly
510(k) Clearance	K081853	Proposed	Proposed
Single Use	Yes		
Shelf-Life Claim	1-year	3-years	1-year
Materials	• Stainless Steel • Delrin/ABS	• Stainless Steel • ABS	• Stainless Steel • ABS • Silicone
Dimensions	Length: 130cm O.D.: 2mm (distal end)		Length: 117cm O.D.: 2mm (distal end)
Suture Mechanism	The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the proprietary suture assembly with the Anchor Exchange to perform stitching operations.		
Compatible Scopes	• Dual channel • OD between 12.8 mm and 14.0 mm • <170 cm length	Olympus • GIF-2TH180 • GIF-2T160	Single Channel Endoscopes that are 8.8 - 9.8 mm in diameter and up to 110cm in working length
Endcap + Scope **Position**	Seats on distal scope face	Seats on distal scope face	Side mount to distal end in any rotational orientation
Attachment	Back-loaded wire	Interference fit	Two straps
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method		

ANCHOR EXCHANGE	Gen 0 Anchor Exchange	Gen 2 Anchor Exchange
510(k) Clearance	K081853	Proposed
Single Use	Yes	
Shelf-Life Claim	1-year	3-years (when packaged as ESS-G02-160) 1-year (when packaged as ESS-G02-Sx1)
Materials	• Stainless Steel • Delrin/ABS	• Stainless Steel • ABS
Dimensions	Length: 130cm O.D.: 3.2mm (distal end)	
Compatible Scopes	• Dual channel • OD between 12.8 mm and 14.0 mm • <170 cm length	<u>Dual Channel</u> Olympus • GIF-2TH180 • GIF-2T160 <u>Single Channel</u>

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ANCHOR EXCHANGE	Gen 0 Anchor Exchange	Gen 2 Anchor Exchange
		Endoscopes that are 8.8 - 9.8mm in diameter and up to 110cm in working length
Method of Actuation	Sliding Lever	Button on top of handle
Integrated With Needle Driver Assembly	Yes	No
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method	

SUTURE CINCH	Gen 0 Suture Cinch	Gen 2 Suture Cinch
510(k) Clearance	K081853	Proposed
Single Use	Yes	
Shelf-Life Claim	1-year	3-years
Materials	• Stainless Steel • ABS • Medical grade metallic or plastic materials	• Stainless Steel • ABS • VESTAKEE PEEK
Cinch design	PEEK or Stainless Plug and collar components designed to press-fit together onto suture and hold construct in place.	PEEK Plug and collar components designed to press-fit together onto suture and hold construct in place.
Dimensions	Suture Cinch Assembly: Length: 182cm O.D.: 2.4mm (distal end) Deployed Cinch: Length: 8mm O.D. 2.4mm	Suture Cinch Assembly: Length: 152cm O.D.: 2.4mm (distal end) Deployed Cinch: Length: 8mm O.D. 2.4mm
User Sequence	Helix, Device Handle, Anchor Exchange, Cinch per DFU	
Compatible Scopes	• Dual channel • OD between 12.8 mm and 14.0 mm • <170 cm length	Dual Channel Olympus • GIF-2TH180 • GIF-2T160 Single Channel Endoscopes that are 8.8 - 9.8mm in diameter and up to 110cm in working length
Method of Actuation	Squeezing of Handle	
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method	

TISSUE HELIX	Gen 0 Tissue Helix	Gen 2 Tissue Helix
510(k) Clearance	K081853	Proposed
Single Use	Yes	
Shelf-Life Claim	1-Year	3-years
Materials	• Stainless Steel • Derlin/ABS	• Stainless Steel • Nitinol • PTFE • ABS
Dimensions	Length: 165cm O.D.: 2.0 mm (distal end)	Length: 165cm O.D.: 2.4mm (distal end)
Compatible Scopes	• Dual channel	Dual Channel

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	• OD between 12.8 mm and 14.0 mm • <170 cm length	Olympus • GIF-2TH180 • GIF-2T160 Single Channel Endoscopes that are 8.8 - 9.8mm in diameter and up to 110cm in working length
Outer Sheath Protecting Coil	No	Yes
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method	

ANCHOR-SUTURE ASSEMBLY	**Gen 0 Anchor**	**Gen 2 Anchor**
510(k) Clearance	K081853	Proposed
Single Use	Yes	
Shelf-Life Claim	1-year	3-years
Materials	• Stainless Steel • Medical Grade Plastic	• Stainless Steel 316L • Cobalt Chromium MP35
Dimensions	Anchor Length: 8.4 mm O.D.: 1.3 mm Suture Length: 185 cm O.D.: 2.0 mm	Anchor Length: 6.6 mm O.D.: 1.0 mm Suture Length: 185 cm O.D.: 2.0 mm
Suture Anchor Design	Suture-Anchor has recessed features on both ends of the component designed to engage with the Needle Body Assembly and the Anchor Exchange. The suture is swaged onto the center of the needle body to allow for the needle body to double as an anchor for the suture construct	Suture-Anchor has a recessed feature on one end designed to engage with the Anchor Exchange, and a latch feature on the opposite end designed to engage with the Needle Body Assembly. The suture is swaged onto the center of the needle body to allow for the needle body to double as an anchor for the suture construct
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method	

Non-Clinical Performance Data: Appropriate product testing was performed on all subject devices 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 protocol. All devices were evaluated to their individual functional and reliability requirements, as well as system compatibility with various endoscopes.

Performance Testing

Bench testing included needle passing reliability, needle pull off strength, Suture Cinch deployment and pull-off strength, Tissue Helix acquisition reliability and bond strength.

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Sterility

Sterility claims (SAL 10^{-6}) were confirmed by executing a sterilization validation in accordance with ISO 11135:2014.

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Shelf-Life

Shelf-life claims were confirmed by repeating sterility and functional testing on aged product.

The results of all studies confirmed equivalency between the subject and predicate devices, and that no new issues of safety or efficacy were raised.

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

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.