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510(k) Summary

AUG 18 2008

General Information

Classification	Class II
Trade Name	OverStitch
Submitter	Apollo Endosurgery, Inc. 7000 Bee Caves Road Suite 350 Austin, Texas 78746 Tel: (512) 328-9990
Contact	Dennis McWilliams President & CEO

Intended Use

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

Predicate Devices

K061770	Endoscopic Suturing System (ESS) Ethicon Endo Surgery
K003956	EndoCinch Suturing System Davol / Bard
K972911	Auto Suture-Endo Stitch Tyco Healthcare

Device Description

The Apollo Endosurgery OverStitch Endoscopic Suture System provides physicians the ability to perform several different types of tissue apposition within the Gastrointestinal

(GI) Tract and peritoneal cavity. Additionally, the system allows the surgeon to 'reload' the suture without the need for removing the endoscope.

Materials

All materials used in the manufacture of the OverStitch are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included mechanical strength testing, bond strength, suture operation, suture securement and visual / dimensional inspection.

Suture placement and securement testing was performed by comparing the OverStitch to commercially available predicate products. The products were used per their respective Instructions for Use. The results showed the OverStitch was equivalent to the predicate devices.

Summary of Substantial Equivalence

The OverStitch is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Apollo Endosurgery, Inc.
% Mr. Dennis McWilliams
President & CEO
7000 Bee Caves Road, Suite 350
Austin, Texas 78746

AUG 18 2008

Re: K081853
Trade/Device Name: OverStitch Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, HCF
Dated: June 26, 2008
Received: June 30, 2008

Dear Mr. McWilliams:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081853

Indications for Use

510(k) Number (if known):

Device Name: OverStitch Endoscopic Suturing System

Indications for Use: The Apollo Endosurgery OverStitch Endoscopic Suture System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081853