K103412

DEC 30 2010

3. Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:

Axiom Technology Partners, LLC.

1351 Third Street, Suite 301

Santa Monica, CA 90401

Date Summary Prepared: November 5, 2010

Contact Person:

James Dreher, Manager

Telephone: 424.744.8773

Fax: 424 744 8774

Device Name:

Trade Name(s): Axiom Fascial Closure System

Classification Name: Laparoscope, General and Plastic Surgery

Panel: General and Plastic Surgery

Product Code: GCJ

Device Description:

A single-use medical device used to close laparoscopic trocar site defects. Closure of laparoscopic trocar site defects is used to reduce the risk of herniation which results in adverse effects to the patient and costly surgical revision by the healthcare provider. The Axiom Fascial Closure System provides mechanical assistance to assure reliable suture placement during fascial closure procedures.

Indications for Use:

The Axiom Fascial Closure Device is used in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

Predicate Device Information:

This device is substantially equivalent to the Covidien EndoClose and the Cooper Surgical Carter-Thomason CloseSure System.

Comparison to Predicate Device(s):

The Axiom Fascial Closure System is substantially equivalent with regard to indications for use, general technological characteristics, principle of operation, and materials.

Summary of Performance Testing

The new device is technologically similar to the predicate device. Device qualification testing has demonstrated:

- Structural integrity of the Axiom Fascial Closure System when subjected to loading
- Forces required to penetrate the bench model with the suture passer for placement of suture
- Biocompatibility of materials used in the construction of the Axiom Fascial Closure System
- Study demonstrating acceptability of suture placement in the bench model

Conclusions

The Axiom Fascial Closure System is substantially equivalent to the Covidien EndoClose and the Cooper Surgical Carter-Thomason CloseSure System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Axiom Technology Partners, LLC
% Quality Management Consulting
Mr. Richard Rush
2939Alhambra Drive
Belmont, California 94002

DEC 3 0 2010

Re: K103412
Trade/Device Name: Axiom Fascial Closure System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, GCJ, HCF
Dated: November 16, 2010
Received: November 22, 2010

Dear Mr. Rush:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

DEC 3 0 2010

Indications for Use

510(k) Number (if known): K103412

Device Name: Axiom Fascial Closure System

Indications For Use

510(k) Number (if known):

The Axiom Fascial Closure Device has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103412