K093253

SafeStitch AMID Stapler 510(k) Summary

NOV 12 2009

Company:	SafeStitch LLC
Contact:	Stewart B. Davis M.D. Chief Operating Officer SafeStitch LLC and SafeStitch Medical Inc. 4400 Biscayne Boulevard Suite A-100 Miami, FL 33137 Phone 305.575.4145 Fax 305.575.4130
Trade Name:	AMID Stapler
Device Type:	Surgical Stapler
Classification Regulation:	878.4750
Class:	II
Panel:	General and Plastic Surgery
Product Code:	GDW
Predicate Devices:	AutoSuture Surgical Stapling Instrument, United States Surgical Corporation, a division of Tyco Healthcare (K771177) AutoSuture Disposable Stapling Instrument, United States Surgical Corporation, a division of Tyco Healthcare (K780695) AutoSuture Titanium Surgical Staples, United States Surgical Corporation, a division of Tyco Healthcare (K855047)
Device Description:	The AMID Stapler is a sterile, single use disposable stapler. The AMID Stapler consists of a manual stapler and 17 titanium staplers. It is designed for the stapling of tissue and mesh, specifically for hernia repairs
Indications for use:	The SafeStitch AMID Stapler has application in general surgery procedures for fixation of mesh, in the repair of hernia defects and in other surgical specialties for the approximation of tissue(s), including skin.

Technological Characteristics:	The SafeStitch AMID Stapler is similar to the predicate devices in design and operation. The primary differences are the firing end does not swivel and the tip is angled.
Performance Data:	Bench testing was performed to verify the AMID Stapler's performance to internal specifications. In addition, bench testing was also performed to demonstrate that the AMID Stapler is substantially equivalent to the predicate device(s).

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

JAN - 4 2010

Safestitch LLC
% Stewart B. Davis, M.D.
Chief Operating Officer
4400 Biscayne Boulevard, Suite A-100
Miami, Florida 33137

Re: K093253
Trade/Device Name: Safestitch LLC AMID Stapler & Non-Absorbable Staples
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: November 12, 2009
Received: November 12, 2009

Dear Dr. Davis:

This letter corrects our substantially equivalent letter of November 12, 2009.

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 (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 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

Indications for Use

510(k) Number (if known): K093253

Device Name: SafeStitch LLC AMID Stapler & Non-Absorbable Staples

The SafeStitch LLC AMID Stapler & Non-Absorbable Staples has applications in general surgery procedures for fixation of mesh, in the repair of hernia defects and in other surgical specialties for the approximation of tissue(s), including skin.

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)

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

510(k) Number K093253