FEB 10 2012

510(k) Summary

This 510(k) Summary is provided per the requirements of 21 CFR 807.92.

Submitter Information:

Name:	SafeStitch Medical, Inc.
Address:	4400 Biscayne Blvd. Miami, FL 33137
Contact Person:	Alina Caraballo Director, Regulatory Affairs and Quality Assurance Telephone: 305-575-4637 Fax: 305-575-4130 Email: acaraballo@safestitch.com

Device Information:

Trade Name:	AMID Stapler®
Common Name:	Surgical Stapler
Classification:	Stapler – Class I; Staple - Class II
Classification Name:	Stapler – Manual surgical instrument for general use; Staple – Implantable staple

Predicate Devices:

The predicate device is the AMID Stapler® that was cleared via 510(k) K093253 on November 12, 2009.

Device Description:

The SafeStitch AMID Stapler™ contains 17 titanium staples. The AMID Stapler™ places a staple each time the instrument's handle is squeezed. The staple legs first penetrate the tissue or mesh and then fully form, thus anchoring or approximating the tissue(s) and/or mesh.

Indications for Use:

The indications for use of the subject device, as described in its labeling, have not changed as a result of the modifications. The indications for use of the subject and predicate devices are identical.

"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 tissues(s), including skin."

Comparison to Predicate Device:

The subject AMID Stapler® is essentially the same as the predicate device with minor modifications and manufacturing process improvements aimed at improving manufacturing efficiencies while maintaining product robustness. These modifications do not change the mechanism of action of the device. In addition, the label and Instructions for Use were revised to better align them with the requirements of 21 CFR 801. To summarize, the subject and predicate devices share the same indications for use, materials, basic design, fundamental scientific technology, labeling, packaging materials and configuration, shelf life, and sterilization processes.

Non-Clinical Testing:

Design verification testing was conducted to verify that the subject device meets the required acceptance criteria and functions equivalent to the predicate device. Results of that testing is presented below:

Test Method	Predicate Device Test Results	Subject Device Test Results
Staple Pull Strength	Pass	Pass
Maximum Staple Penetration	Pass	Pass
Formed Staple Height	Pass	Pass
Formed Staple Width	Pass	Pass
Maximum Deployment Force	Pass	Pass

Substantial Equivalence:

In establishing substantial equivalence to the predicate device, SafeStitch Medical, Inc. evaluated the indications for use, materials, basic design, fundamental scientific technology, labeling, packaging materials and configuration, shelf life, and sterilization processes. The performance testing included in this submission demonstrates that the differences between the subject and predicate devices do not impact safety and effectiveness. Thus, based on the information presented herein, the subject AMID Stapler® is substantially equivalent to the predicate AMID Stapler® cleared via 510(k) K093253 on November 12, 2009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 10 2012

SafeStitch Medical, Inc.
% Ms. Alina Caraballo
4400 Biscayne Boulevard, Suite 670
Miami, Florida 33137

Re: K120268
Trade/Device Name: Amid Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: January 27, 2012
Received: January 30, 2012

Dear Ms. Caraballo:

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

Indications for Use

510(k) Number (if known):

Device Name: AMID Stapler®

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.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Kwon for MKM

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

510(k) Number K120268