K132669

SECTION 5: 510(k) SUMMARY STATEMENT

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

JAN 13 2014

1. **General Information**
   Date of Submission: August 26, 2013

   Submitted By: Surgimatix, Inc.
   1539 Jarvis Street
   Elk Grove Village, IL 60007

   Contact Person: Grace Carlson, MD
   Director, Regulatory and Clinical Affairs
   Phone 847-400-2546
   Fax 847-258-3326
   gcarlson@surgimatix.com

2. **Trade/Proprietary Name of Device:**

Trade Name:	ProxiFast™ Absorbable Staple
Common Name:	Staple, Implantable
Regulation Number	878.4750
Product Code:	GDW
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

3. **Legally Marketed Predicate Devices for Claimed Equivalence:**
   Name: INSORB Absorbable Staple
   510(k) #: K090159

   The Ethicon PDS™ Barbed Suture (K113004) is being referenced as a device made of polydioxanone. Therefore, the use of polydioxanone as a suture or fastener material is not new.

4. **Device Description**
   The ProxiFast Absorbable Staple is an absorbable staple for subcuticular skin closure. The staple is made of polydioxanone, and consists of a main body that is 19.35 mm in length, with an obround loop at either end, each of which measure 2.74 by 4.72 mm. The staple is formed into an s-shape the size of 10.3 mm x 17.3 mm prior to deployment, and forms a helical configuration when placed into the subcuticular skin. The Proxifast Absorbable staples are used in conjunction with a manual surgical stapler from Surgimatix, Inc. (Note: The Surgimatix manual surgical stapler is a Class I exempt device pursuant to 21 CFR 878.4800 and is not the subject of this submission).

5. Indications for Use Statement

ProxiFast Absorbable Staples are intended for use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin with an approximate thickness of 1 to 5 mm where an absorbable tissue fastener is desired for temporary tissue approximation.

The device is not indicated for use in shallow or very small incisions, and is not indicated for final closure of the terminal 2 cm of incisions.

6. Substantial Equivalence Comparison

Indications for Use

Substantial equivalence for the ProxiFast Absorbable Staple is supported by the predicate device listed in this submission, which has a similar indications statement. The Indications for Use Statement for the ProxiFast Absorbable Staple provides additional specificity with respect to the range of skin thicknesses for which the device is applicable compared to the predicate device.

Technological Characteristics

Key technological characteristics of the ProxiFast Absorbable Staple are similar to the predicate device:

The ProxiFast Absorbable Staple is manufactured from polydioxanone, whereas the predicate device is made from a polyglycolic/polylactic acid copolymer. Both polydioxanone and polyglycolic/polylactic acid copolymer are bioresorbable materials commonly used in the manufacture of absorbable surgical sutures. Both materials have similar strength profiles and comparable absorption time profiles.

The ProxiFast Absorbable Staple has a slightly different size and shape than the predicate device in its native configuration; however, once placed into the tissue, the size is roughly comparable.

The ProxiFast Absorbable Staple is a single use, sterile implantable device, sterilized by ethylene oxide. The predicate device is also a single use, sterile implantable device, sterilized by gamma irradiation. Both ethylene oxide and gamma irradiation are commonly used methods for the sterilization of implantable medical devices.

Performance Data

Mechanical, biocompatibility, and preclinical data, including a chronic animal study, confirmed that the ProxiFast Absorbable Staple performs as intended and that no new issues of safety and effectiveness are introduced. Functional and deployment testing in tissue demonstrated that the ProxiFast Absorbable Staple can be used for subcuticular closure in a range of skin thicknesses comparable to the predicate device. Mechanical testing following deployment in tissue

demonstrated that the ProxiFast Absorbable Staple has a tensile strength comparable to the predicate device.

7. **Conclusion**

The ProxiFast Absorbable Staple is substantially equivalent to the predicate device currently marketed in accordance with the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 13, 2014

Surgimatix
Dr. Grace Carlson
Director, Regulatory and Clinical Affairs
1539 Jarvis Avenue
Elk Grove Village, Illinois 60007

Re: K132669
Trade/Device Name: Surgimatix ProxiFast Absorbable Staple
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 12, 2013
Received: December 13, 2013

Dear Ms. Carlson:

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132669

Device Name
Surgimatix ProxiFast Absorbable Staple

Indications for Use *(Describe)*
Surgimatix ProxiFast Absorbable Staples are intended for use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin with an approximate thickness of 1 to 5 mm where an absorbable tissue fastener is desired for temporary tissue approximation.

The device is not indicated for use in shallow or very small incisions, and is not indicated for final closure of the terminal 2 cm of incisions.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S