October 1, 2021

Surgimatix, Inc.
Dorene Markwiese
Director of Regulatory Affairs
1539 Jarvis Ave
Elk Grove Village, Illinois 60007

Re: K201934
Trade/Device Name: Surgimatix Absorbable Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 1, 2021
Received: September 2, 2021

Dear Dorene Markwiese:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Deborah Fellhauer
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201934

Device Name
Surgimatix Absorbable Fixation System

Indications for Use *(Describe)*
The Surgimatix Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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

1. **General Information**
   Date of Submission: June 29, 2020

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

   Contact Person: Dorene Markwiese
   Director of Regulatory Affairs
   Phone 847-400-2546
   Fax 847-258-3326
   dmarkwiese@surgimatix.com

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

Trade Name:	Surgimatix Absorbable Fixation System
Common Name:	Staple, Implantable
Regulation Number	878.4750
Product Code:	GDW
Device Panel:	General and Plastic Surgery
Device Classification:	Class II

3. **Legally Marketed Predicate Devices for Claimed Equivalence:**
   Name: Davol Absorbable Fastener System
   510(k) #: K082396

   The SorbaFix Absorbable Fixation System (K111153) and the Surgimatix Proxifast Absorbable Staple (K132669) are reference devices for this submission.

4. **Device Description**
   The Surgimatix Absorbable Fastener System is designed to deliver an absorbable fastener for tissue-to-tissue fixation or mesh-to-tissue fixation during surgical procedures. The deployment device consists of an ergonomic handle with trigger, shaft and tip. The shaft is 38 cm long, and can be utilized for laparoscopic or open surgical procedures. The device is preloaded with 20 polydioxanone absorbable fasteners. During deployment into soft tissue or mesh the absorbable fastener is formed into a helical configuration to establish fixation.

5. **Indications for Use Statement**

The Surgimatix Absorbable Fixation System is intended for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

6. **Substantial Equivalence Comparison**

Indications for Use:

Substantial equivalence for the Surgimatix Absorbable Fixation System is supported by the predicate device listed in this submission, which has an identical indications statement.

Technological Characteristics:

Key technological characteristics of the Surgimatix Absorbable Fixation System are similar to the predicate device. Both devices have the same basic components including a handle and shaft designed to deliver a fastener. Both devices use similar fixation technology to deliver a fastener by activating a trigger.

The Surgimatix absorbable fasteners are manufactured from polydiaxonone, whereas the predicate absorbable fasteners are manufactured from poly (D,L) lactide. The materials are both commonly used for implantable sutures or fasteners. The Surgimatix absorbable fastener material is identical to the material utilized for the Surgimatix Proxifast Absorbable Staple (K132669), referenced within this submission.

The proposed device and the predicate device differ in the details of the device design. The proposed device utilizes opposing needles at the tip to deliver the fastener into a helical configuration in the soft tissue or mesh. The predicate device has fasteners that are screw like which are driven into the tissue or mesh using a needle. The functional result of each device is equivalent as the end effect is to effectively place a fastener into tissue and/or mesh for fixation.

Mechanical, biocompatibility, and preclinical data confirmed that the Surgimatix Absorbable Fixation System performs as intended and that no new issues of safety and effectiveness are introduced. The Surgimatix Absorbable Fasteners were tested in vivo in an animal model to confirm the mechanical strength of the repair over time as compared to the predicate device**.**

7. **Conclusion**

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