August 1, 2018

Surgical Innovation Associates, Inc.
% Ms. Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K181094
Trade/Device Name: Polydioxanone Surgical Scaffold™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWT
Dated: July 3, 2018
Received: July 3, 2018

Dear Ms. Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181094

Device Name
Polydioxanone Surgical Scaffold

Indications for Use *(Describe)*
Polydioxanone Surgical Scaffold is indicated for use in reinforcement of soft tissue where weakness exists.

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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510(k) SUMMARY

Surgical Innovation Associates' Polydioxanone Surgical Scaffold™

Applicant

Surgical Innovation Associates, Inc.
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Date Prepared: July 31, 2018

Device

510(k) Number K181094
Trade Name: Polydioxanone Surgical Scaffold™
Common Name: Surgical Mesh
Classification Name: Mesh, Surgical, Polymeric
Regulatory Class: Class II
Product Code: OWT

Predicate Device

Novus Scientific AB, TIGR® Matrix Surgical Mesh, K163005, K092224

Intended Use / Indications for Use

Polydioxanone Surgical Scaffold™ is intended for use in reinforcement of soft tissue where weakness exists.

Device Description

Polydioxanone Surgical Scaffold™ is a resorbable, colorless, monofilament knit surgical mesh. Polydioxanone Surgical Scaffold™ is packaged individually and is provided sterile as a flat mesh that can be cut to the desired shape and size. Polydioxanone Surgical Scaffold™ is made entirely of uncolored and undyed polydioxanone (PDO) thread, which is similar in form to PDO sutures. The threads degrade via bulk hydrolysis once implanted. Strength retention decreases followed by mass loss in the threads. In vitro degradation studies show that Polydioxanone Surgical Scaffold™ threads retain some burst strength for 3 months, but not beyond that time. In vivo implantation studies in swine demonstrate that Polydioxanone Surgical Scaffold™ takes up to 9 months to fully absorb.

Technological Characteristics

The subject Polydioxanone Surgical Scaffold™ has very similar technological characteristics compared to the predicate TIGR® Matrix Surgical Mesh. Physical and mechanical properties such as mesh thickness, density, pore diameter, mesh knit characteristics, suture pull-out strength, tear strength, tensile strength, and burst strength are all similar between the products.

Performance Data

Bench Testing

Comparison to the predicate device was performed for:

- Dimensions
- Ball burst strength - ASTM D3787, Standard Test Method For Bursting Strength of Textiles – Constant Rate of Traverse (CVT) Ball Burst Test
- Suture pullout strength
- Tear strength - ASTM D2261, Standard Test Method For Tearing Strength of Fabrics By The Tongue (Single Rip) Procedure (Constant-Rate-of-Extension Tensile Testing Machine
- Stiffness - ASTM D1388, Standard Test Method For Stiffness of Fabrics
- Tensile strength - ASTM D5035, Standard Test Method or Breaking Force and Elongation of Textile Fabrics (Strip Method).

Both devices had suitable characteristics for their indication for use.

A seventeen-week *in vitro* hydrolytic degradation study guided by ASTM F1635-16 Standard Test Method For In Vitro Degradation Testing of Hydrolytically Degradable Polymer Resins And Fabricated Forms For Surgical Implants was also performed. This study provided confirmation of both the duration to full strength loss and the anticipated time to full absorption as determined by serial molecular weight measurements.

Biocompatibility Testing

Polydioxanone Surgical Scaffold™ was tested according to ISO 10993 Biologic Evaluation of Medical devices. Polydioxanone Surgical Scaffold™ was found to be non-cytotoxic, non-irritating and non-sensitizing. Polydioxanone Surgical Scaffold™ exhibited no systemic toxicity. It was non-pyrogenic and non-mutagenic. It was also found to be hemocompatible. Polydioxanone Surgical Scaffold™ was non-reactive after a 4-week intramuscular implantation study. A 12-week implantation-based test for subchronic systemic toxicity was negative, and the implant sites demonstrated expected observations histologically.

Animal Study

A porcine study comparing Polydioxanone Surgical Scaffold™ to the predicate device was conducted for 90 days with interim data gathered at 30 days. Hematology and serum chemistry were studied at 0, 30, and 90 days. Mechanical testing comparisons were done. Also, local host responses were characterized. Molecular weight was determined at days 0, 30, and 90. At all time points tissue site strength was either not statistically different between sites repaired with Polydioxanone Surgical Scaffold™ and TIGR® Matrix Surgical Mesh or sites repaired with Polydioxanone Surgical Scaffold™ had significantly greater strength.

Substantial Equivalence

Based on the information provided herein, Polydioxanone Surgical Scaffold™ is substantially equivalent to the predicate, TIGR® Matrix Surgical Mesh. Polydioxanone Surgical Scaffold™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between

Polydioxanone Surgical Scaffold™ and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that Polydioxanone Surgical Scaffold™ is as safe and effective as TIGR® Matrix Surgical Mesh**.** Thus, Polydioxanone Surgical Scaffold™ is substantially equivalent.

Conclusion

Polydioxanone Surgical Scaffold™ is substantially equivalent to TIGR® Matrix Surgical Mesh in indications for use and technological characteristics. Testing of material properties, biocompatibility, and bench testing showed both products have suitable characteristics for their indications for use.