July 12, 2019

Origami Surgical
Mr. John Gillespie
Management Representative
42 Main St. Suite A
Madison, New Jersey 07940

Re: K191317
Trade/Device Name: StitchKit®
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY, GCJ, NAY
Dated: May 13, 2019
Received: May 15, 2019

Dear Mr. Gillespie:

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,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

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)*
K191317

Device Name
StitchKit® Suture Deliver Canister with PTFE Surgical Suture

Indications for Use *(Describe)*
The StitchKit® device facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing.
Monotex® PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. Monotex® PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. Monotex® PTFE suture is provided sterile as a single use device.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

Submitter: Origami Surgical LLC, 42 Main Street, Suite A, Madison, NJ 07940
Phone: 1-973-765-6256, Fax Number: 1-973-695-1045
Registration Number: 3010860245

Contact Person: John Gillespie, info@stitchkit.com

Date of Preparation: May 13, 2019

Device Trade Name: StitchKit®

Common Name: Suture Delivery Canister

Classification: Class: II; Panel: General and Plastic Surgery
Regulation (Primary): 878.5035 Nonabsorbable Expanded, Polytetrafluoroethylene Surgical Suture.
Product code NBY; Secondary Codes: GCJ and NAY

Predicate Devices: K123811 StitchKit® Suture Delivery Canister
K140415 Riverpoint Medical Monotex® PTFE Suture

Device Description: StitchKit® is a suture delivery canister which facilitates endoscopic robotic surgery by introducing multiple strands of suturing materials to the surgical site at one time and allowing for the safe retrieval of the needles.

Indication for Use:

The StitchKit® device facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing.

Monotex® PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. Monotex® PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. Monotex® PTFE suture is provided sterile as a single use device.

Description of Change:

This submission is related to a change to this existing legally marketed device. The differences between the original and changed device are: (1) alternate source for suture; (2) the choice of finish on stainless steel needle; and (3) longer shelf life based on real-time age testing. The Indication for Use for the StitchKit device incorporates the cleared Indication for use for the suture contained within. Hence the indication for use has been modified to align with that of the suture contained within.

These differences do not raise questions of safety or effectiveness.

Performance Data:

The following tests were performed to support the changes described:

1. Suture tensile strength	5. LAL Pyrogen	9. Real-time Age
2. Needle Pull-Off	6. Material Mediated Pyrogen	
3. Suture diameter	7. Usability Evaluation	
4. Suture strand length	8. Comparative Physico-Chemical Extraction	

Summary of Substantial Equivalence:

Based on the comparison to predicate and on test results we conclude the changes do not raise new questions of safety and efficacy, and that the changed device is substantially equivalent to its predicate, the original, unchanged device.