February 14, 2023

Origami Surgical Inc .
John Gillespie
Management Representative
42 Main St.
Madison, New Jersey 07940

Re: K221527
Trade/Device Name: StitchKit
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: May 24, 2022
Received: May 26, 2022

Dear John 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 and Part 809); 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 A. Fellhauer
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Deborah Fellhauer, RN, BSN
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)*
K221527

Device Name
StitchKit®

Indications for Use *(Describe)*
StitchKit® Suture Delivery Canister facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The suture contained within the device is intended for soft tissue approximation where use of the specific absorbable or non-absorbable sutures contained within it is appropriate

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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510(k) Summary

Manufacturer: **K221527**
Origami Surgical Inc.,
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: jgillespie@origamisurgical.com

Preparation Date: February 9, 2023

Trade/Device Name: StitchKit®

Common Name: Suture Delivery Canister

Classification: Class: II
Panel: General and Plastic Surgery
Product Code: GAM (Primary), GAT, GCJ and NAY

Regulation Number: 21 CFR 878.4493

Regulation Name: Absorbable Poly (Glycolide/L-Lactide) Surgical Suture

Devices to Which the Device is Substantially Equivalent:

- K211792: StitchKit®, product code GAM (Primary), GAT, GCJ and NAY

Device Description:

StitchKit® is a sterile, single-use plastic canister that is provided pre-loaded with suturing materials with attached needles. The device facilitates endoscopic robotic surgery by introducing multiple strands of suture to the surgical site at one time and allowing for the safe retrieval of the needles. The canister is sized to be passed through a ≥12 mm trocar or passed through an incision sized for an 8 mm trocar under direct endoscopic visualization. As suturing is completed with each strand, the used needle is placed into a compartment within the canister for safekeeping until the entire canister is removed either through the ≥ 12 mm trocar or through the 8mm trocar incision in tandem with the 8mm trocar, also under direct endoscopic visualization using the attached retrieval string. It is supplied sterile.

Indication for Use:

StitchKit® Suture Delivery Canister facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The suture contained within the device is intended for soft tissue approximation where use of the specific absorbable or non-absorbable sutures contained within it is appropriate.

Comparison to Predicate:

This submission relates to a modification of the instructions for use of an existing device. There is no change to the Intended Use, Indications for Use Statement, nor Technological Characteristics. The proposed change is for modifications to the Instructions for Use for the device, which previously stated that the device may only be inserted or removed via a ≥ 12 mm trocar. The revised instructions add that the device may alternatively be

inserted or removed through an existing 8 mm trocar site incision under direct endoscopic visualization by removing the trocar and placing the device through that incision into the surgical field.

This submission was also supported by a retrospective case review clinical study (n=422) conducted by an academic medical center.

Performance Data

A functional performance test consisting of simulated surgical testing in an animal model was conducted. This included insertion and removal through an 8 mm trocar site in the model to demonstrate that the technique is compatible with the StitchKit device.

Conclusion:

Based on the unchanged Indication for Use and Technological Characteristics; functional test data; clinical data; and comparison to the predicate device including risk analysis; we conclude that the proposed StitchKit® device is substantially equivalent to its predicate.