February 23, 2021

Origami Surgical
John Gillespie
Management Representative
79 Haven St.
Dover, Massachusetts 02030

Re: K202950
Trade/Device Name: StitchKit COMBO
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, GAP, GCJ, NAY
Dated: January 18, 2021
Received: January 21, 2021

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); 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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K202950

Device Name
StitchKit® COMBO Suture Delivery Canister

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 StitchKit® 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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6. 510(k) Summary (revised 2/19/21)

Manufacturer: Origami Surgical Inc.
42 Main Street, Suite A, Madison, NJ 07940
Phone: 1-973-765-6256, Fax Number: 1-973-695-1045
Registration Number: 301086024507940

Contact Person: John Gillespie: jgillespie@origamisurgical.com

Date of Preparation: August 21, 2020

Trade/Device Name: StitchKit® COMBO

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

Regulation Number: 21 CFR 878.4493

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

Legally Marketed Devices to Which the Device is Substantially Equivalent:

- K173874: StitchKit® V-Loc™ 90, StitchKit® V-Loc™ 180, StitchKit® Quill® PDO
- K981935: Polysorb™ Suture
- K980124: SofSilk™ Suture

Device Description:

StitchKit® COMBO is a suture delivery canister which facilitates endoscopic robotic surgery by introducing multiple strands of different suturing materials to the surgical site at one time and allowing for the safe retrieval of the needles. It is sized to be passed through a ≥12 mm trocar. As suturing is completed with each strand, the used needle is placed into a disposal compartment within the canister for safekeeping until the entire canister is removed through the trocar using the attached retrieval string. It is supplied sterile in a foil pouch. Each StitchKit® version contains strands of existing legally-marketed Suturing Materials, cleared for use within the StitchKit®. The subject StitchKit® versions contain:

- StitchKit® COMBO SK-103: Polysorb®, Vloc™-180, and Vloc™-90
- StitchKit® COMBO SK-104: Polysorb®, SofSilk®, and Vloc™-90
- StitchKit® COMBO SK-105: Polysorb®, and Vloc™-90

Figure 1, below, illustrates how each suture exits the device through a unique Exit Hole labelled to identify the suture types. In an actual COMBO device the generic labels S1 through S6 are replaced with short labels identifying the actual sutures within the device.

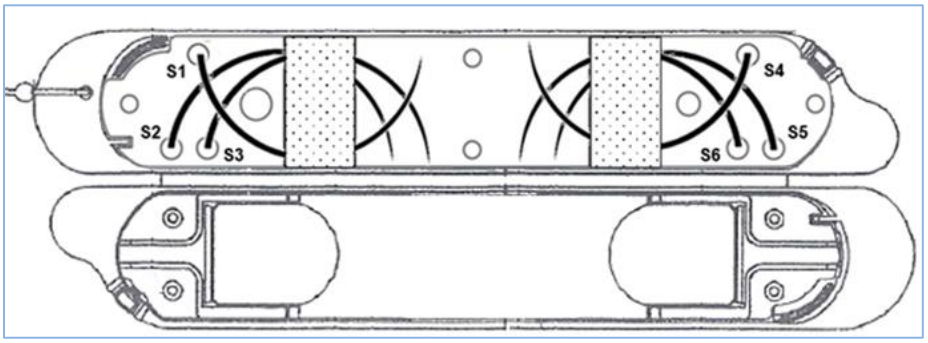

Figure 1 StitchKit® COMBO™ in its open configuration, showing suture labels

Indications for Use Statement:
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 StitchKit® device is intended for soft tissue approximation where use of the specific absorbable or non-absorbable sutures contained within it is appropriate.

Technological Characteristics:
With regard to Technological Characteristics, the subject StitchKit® versions are substantially equivalent to the predicate in that:

- The canister portion consists of the actual predicate canister portion.
- The implantable portions consist of the actual predicate wound closure materials as supplied by their respective manufacturers. They have not been modified, just packaged within the StitchKit® canister.

Performance Data
Performance testing has been performed in support of the intended use of these devices. This testing verifies that the subject StitchKit® versions are substantially equivalent to the predicate devices. The test data includes:

- Suture functional testing including
  - knot-pull tensile testing,
  - diameter
  - needle attachment
- Comparative *in-vitro* simulated biodegradation testing
- Stability Evaluations
- LAL Pyrogen testing
- Comparative Physico-Chemical analysis
- Material Mediated Rabbit Pyrogen testing

Conclusion:
Based on the Indication for Use, Technological Characteristics, Test Data, and comparison to its predicate devices we conclude that the proposed StitchKit® device has been shown to be substantially equivalent to its predicate devices.