May 4, 2018

Origami Surgical LLC
% Mr. John Gillespie
Consultant
Clover Medical LLC
79 Haven St.
Dover, Massachusetts 02030

Re: K173874
Trade/Device Name: StitchKit® V-Loc 90, StitchKit® V-Loc 180, StitchKit® Quill PDO
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, NEW, GCJ, NAY
Dated: December 18, 2017
Received: December 21, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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)*

K173874

Device Name

StitchKit® V-Loc™ 90, StitchKit® V-Loc™ 180, StitchKit® Quill™ PDO

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 within this StitchKit® device is intended for soft tissue approximation where use of an absorbable suture 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.

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5. 510(k) Summary

Submitter: Origami Surgical, LLC
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Contact Person: John Gillespie (Consultant)
Phone: 1-973-765-6256
Fax Number: 1-973-695-1045
Email: info@stitchkit.com

Date of Preparation: December 18, 2017
Date updated: March 5, 2018

Device Trade Name: StitchKit® V-Loc™ 90
StitchKit® V-Loc™ 180
StitchKit® Quill™ PDO

Common Name: Suture Delivery Canister

Classification: Class: II
Panel: General and Plastic Surgery
Product Code (Primary): GAM, 21 CFR 878.4493
(Secondary): NEW, GCJ and NAY

Legally Marketed Devices to Which the Device is Substantially Equivalent:

- K123811: StitchKit® Suture Delivery Canister with ePTFE Surgical Suture
- K100257: V-Loc™ 90 Absorbable Wound Closure Device
- K091087: V-Loc™ 180 Absorbable Wound Closure Device
- K051609: Quill™ Synthetic Absorbable Polydioxanone Barbed Suture.

Description of Device

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. 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 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. The subject StitchKit® versions contain:

- StitchKit® V-Loc™90: Contains Covidien V-Loc™90 Wound Closure Devices
- StitchKit® V-Loc™180: Contains Covidien V-Loc™180 Wound Closure Devices
- StitchKit® Quill™ PDO: Contains Quill™ PDO Synthetic Absorbable Barbed Sutures

Intended 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 within this StitchKit® device is intended for soft tissue approximation where use of an absorbable suture is appropriate.

Technological Characteristics:

With regard to Technological Characteristics, the subject StitchKit® versions are substantially equivalent to the predicates 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
- ETO Residuals

- LAL Pyrogen testing
- Comparative Physico-Chemical analysis
- Material Mediated Rabbit Pyrogen testing
- 2 Week Implantation study, followed by Histopathology 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.