



July 16, 2021

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

Re: K211792

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: June 9, 2021  
Received: June 10, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Cindy Chowdhury, Ph.D., MBA  
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

## Indications for Use

510(k) Number (if known)

K211792

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.

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## 510(k) Summary

**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: 3010860245

**Contact Person:** John Gillespie: [jgillespie@origamisurgical.com](mailto:jgillespie@origamisurgical.com)

**Date of Preparation:** June 9, 2021

**Trade/Device Name:** StitchKit® additional sutures

**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 [product code]:

- K202950: StitchKit® COMBO, [GAM (Primary), GAP, GCJ and NAY]
- K000037: Biosyn™ Monofilament Absorbable Sutures, [GAM];
- K990951: Maxon™ Monofilament Absorbable Sutures, [GAM];
- K103052: V-Loc™ PBT Non-Absorbable Wound Closure Device, [GAT];
- K930591: Ti-Cron™ Braided Polyester Sutures, [GAT].

### Device Description:

StitchKit® 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  $\geq 12$  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. Each StitchKit® contains strands of existing legally-marketed Suturing Materials, cleared for use within the device.

### 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 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 StitchKit® canister with additional sutures is substantially equivalent to the predicates in that:

- The canister is legally marketed and unchanged.
- The sutures are legally marketed and have not been modified. They are only trimmed to length, if needed, and packaged within the StitchKit(R) 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:

- Comparative Physico-Chemical analysis
- LAL Pyrogen testing
- Material Mediated Pyrogen testing
- Stability Evaluations including USP suture tensile strength, diameter, and needle attachment testing
- Comparative *in-vitro* simulated biodegradation testing for the absorbable sutures

**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.