December 1, 2017

SutureEase, Inc.
Mr. Scott Heneveld
Chief Operating Officer
1735 N First Street, Suite 300
San Jose, California 95112

Re: K172666
Trade/Device Name: CrossBow Fascial Closure System, CrossBow Fascial Closure System with Adaptor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW, HCF
Dated: August 28, 2017
Received: September 5, 2017

Dear Mr. Heneveld:

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

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)*

Device Name
CrossBow Fascial Closure System

Indications for Use *(Describe)*
This product is intended to pass suture through soft tissue layers (fascia, muscle and peritoneum) of a trocar wound at the end of laparoscopic surgery.
It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. 510K SUMMARY

Manufacturer
Suture Ease, Inc.
1735 N First Street, Suite 300
San Jose, California 95112

Contact Person
Scott Heneveld
COO
(408) 459-7595

Trade Name: CrossBow Fascial Closure System
Common / Usual Name: Endoscopic tissue approximation device
Classification Name: Endoscope and Accessories
Regulation Number: 21 CFR 876.1500
Device Class: II
Product Code: HCF, OCW
Predicate Device: Weck EFx Fascial Closure System, K132362

Device Description

The CrossBow Fascial Closure System is a set of single-use instruments primarily intended for the use of closing soft tissue layers (fascia, muscle and peritoneum) of a trocar wound following laparoscopic surgery. The CrossBow Fascial Closure System has two basic components: (1) a suture passer component used to pass suture through the abdominal wall, and (2) a guide used to repeatedly direct the needle through the abdominal wall using visual markers to reference the needle puncture location off the inner wall of the abdomen. The guide has two deployable snare loops used to secure and retrieve the free ends of suture passed by the suture passer. The device also has an accessory adaptor to accommodate larger size port defects.

Intended Use / Indications

1.1 Intended Use:
The device is intended to provide the function of aiding in the closure of the fascia/peritoneum at the trocar sites at the end of a laparoscopic procedure.

1.2 Indication for Use:
1.2.1 This product is intended to pass suture through soft tissue layers (fascia, muscle and peritoneum) of a trocar wound at the end of laparoscopic surgery.
1.2.2 It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.

1.3 Contra-Indications:
The device is subject to the following contra-indications:

1.3.1 This device is not intended for use where endoscopic techniques are contraindicated.
1.3.2 Do NOT use the CrossBow device where it is not possible to visualize the tip of the needle during insertion or removal.
1.3.3 The device is not intended for use when the minimum tissue thickness does not reach the markings on the guide component.

Summary of Non-Clinical Performance Data

The following non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate devices;

Validation and/or Verification Method	Acceptance Value/Criteria	Verification and Validation Results
Mechanical Testing (Needle Penetration)	To require comparable or less penetration force than competitive devices	Acceptable
Mechanical Testing (Snare Loop Integrity)	To exceed the strength of the expected loading requirements	Acceptable
Mechanical Testing (Needle Security in Passer)	To exceed the strength of the expected loading requirements	Acceptable
Mechanical Testing (Guide Suture Security)	To exceed the strength of the expected loading requirements	Acceptable
Mechanical Testing (Targeting & No. of Uses)	To provide accurate performance and expected number of uses	Acceptable
Surgeon Validation Lab (Animal model)	Successful placement of suture and closure of defect	Acceptable

The CrossBow Fascial Closure System tested met the predetermined acceptance criteria. Based on the results of the testing, the CrossBow Fascial Closure System is safe and effective for its intended use.

Biocompatibility

The biocompatibility evaluation for the CrossBow Fascial Closure System was conducted in accordance with the International Standard ISO 10993-1: "Biological Evaluation of Medical Devices −Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA.

Biomaterial testing was performed on the device components individually and the following tests were conducted on the finished, completed device after gamma sterilization:

- Cytotoxicity
- Irritation
- Sensitization
- Material Mediated Pyrogenicity
- Hemocompatibility

According to ISO 10993-1: "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" the CrossBow Fascial Closure System is categorized as:

- Externally Communicating
- Blood Contacting
- Less than 24 hours

Conclusion

The CrossBow Fascial Closure System is substantially equivalent in intended use and fundamental scientific technology as the Weck EFx Endo Fascial Closure System (K132362). The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.