March 13, 2019

Via Surgical Ltd.
% Mr. Leo Basta
Owner
Northstar Biomedical Associates
93 Benefit Street
Providence, Rhode Island 02904

Re: K181668
Trade/Device Name: FasTouch Absorbable Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 22, 2018
Received: June 25, 2018

Dear Mr. Basta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Joseph Nielsen -S

Digitally signed by Joseph Nielsen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joseph Nielsen -S, 0.9.2342.19200300.100.1.1=2000367505
Date: 2019.03.13 13:22:02 -04'00'

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)*
K181668

Device Name
FasTouch Absorbable Fixation System

Indications for Use *(Describe)*
The FasTouch Absorbable Fixation System is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional Premarket Notification Submission – 510(k)
FasTouch Absorbable Fixation System

Date Prepared: June 19, 2018

I. SUBMITTER

Via Surgical Ltd.
Mitzpe Kineret Street 22/1
Moshav Amirim, 20115, Israel
Tel: +972-52-639-5765
Fax: +972-153-77-500-8214

Contact Person
Leo Basta
Northstar Biomedical Associates for
Via Surgical Ltd.
755 Westminster Street Unit 120
Providence, RI 02903
617.834.9866 (phone)
401.454.1733
lbasta@northstarbiomedical.com

and/or
Orly Maor
25A Sirkin Street
Kfar Saba 44421, Israel
Tel: +972-9-7453607
Fax: +972-153-9-7453607
oram.ma@gmail.com

II. DEVICE

Name of Device: FasTouch Absorbable Fixation System

Common or Usual Name: FasTouch Absorbable Fixation System

Classification Name: Implantable staple, Regulation No. 878.4750
Regulatory Class: II

Via Surgical

Product Code: GDW

III. PREDICATE DEVICE

Via Surgical Ltd. believes that the FasTouch Absorbable Fixation System is substantially equivalent to the following predicate device:

- Via Surgical FasTouch Fixation System cleared under K162252 and (product code GDW Regulation No. 878.4750) and K132698 (original submission).

In addition, the Optifix™ Absorbable Fixation System (C.R. BARD, Inc) cleared under K132134 (product code GDW, Regulation No. 878.4750) is being used as a reference device for its technological characteristics of the fastener used for the same clinical intended use.

IV. DEVICE DESCRIPTION

The FasTouch Absorbable Fixation System is a disposable, sterile single-use system designed to deliver absorbable fastener into tissue and prosthesis during general surgery procedures such as hernia repair.

The Via Surgical FasTouch Absorbable Fixation System, is designed to be inserted through a 5mm or larger laparoscopic port sleeve.

The fasteners two ends are designed to be locked together in the tissue by the FasTouch firing mechanism, thus forming a closed locked loop into the tissue affixing the surgical mesh to the tissue. The fasteners are absorbable and made of PURASORB PLG 8218 dye with D&C violet No. 2.

V. INDICATIONS FOR USE

The FasTouch Absorbable Fixation System is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The FasTouch Absorbable Fixation System has the same intended use as the predicate device. In addition, the subject device has the identical indications for use to that of the reference device. The dimensions of the FasTouch Absorbable Fixation System are identical to the predicate. Similar tests and test methods performed in accordance

with the same standards were used in both FasTouch Absorbable Fixation System and the predicate device to validate the design. The testing results showed that the minor differences in device characteristics between the subject devices and predicate devices do not raise any new questions of safety or effectiveness.

The FasTouch Absorbable Fixation System have the same technological characteristics as the predicate device and as the reference device as demonstrated in the SE table below:

Based on the above analysis, Via Surgical Ltd. believes that the FasTouch Absorbable Fixation System is substantially equivalent to the legally marketed predicate device.

	FasTouch Absorbable Fixation System	FasTouch Fixation System	SE Justification
510(k) Number	Not yet known	K132698 and K162252	
Manufacturer	Via Surgical Ltd.	Via Surgical Ltd.	Same
Product Code	GDW	GDW	Same
CFR	878.4750	878.4750	Same
Intended Use & Indications for Use	The FasTouch Absorbable Fixation System is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.	The FasTouch Fixation Device is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs	Same
Environments of Use	Hospitals, sub-acute care institutions and surgery center	Hospitals, sub-acute care institutions and surgery center	Same
Patient Population	Individuals undergoing surgical procedure in which prosthetic mesh is being implanted	Individuals undergoing surgical procedure in which prosthetic mesh is being implanted	Same
Delivery Device Design	Handles with trigger "piston" grip	Handles with trigger "piston" grip	Same
Loading	Cartridge can be loaded in OR	Cartridge can be loaded in OR	Same

	FasTouch Absorbable Fixation System	FasTouch Fixation System	SE Justification
Shaft Length	35.7cm	35.7cm	Same
Firing Mechanism	Spring-load	Spring-load	Same
Penetration Depth	6.1mm	6.1mm	Same
Number of Fasteners	25	25	Same
Fastener Material	PLGA8218 dyed with D&C 2 colorant 0.05% (a copolymer of L-lactide and Glycolide in a 82/18 molar ratio)	Non - absorbable polymer (PCU)	Same as the reference device Optifix Absorbable Fixation System cleared under K132134
Fastener Design	Strap - suture like	Strap - suture like	Same
Single Patient Use, Disposable	Yes	Yes	Same
Sterilization	Sterile for single use EtO	Sterile for single use EtO	Same
Prescription Use	The device should be used only by trained surgeon under a physician order.	The device should be used only by trained surgeon under a physician order.	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Risk analysis** per ISO 14971:2012
- **Biocompatibility testing**

  An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility evaluation included:

#	Test	Standard
1	Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5: 2009

#	Test	Standard
2	Irritation - ISO Intracutaneous Study	ISO 10993-10: 2010
3	Systemic Toxicity Study	ISO 10993:11:2010
4	ISO Maximization Sensitization Test	ISO 10993-10: 2010
5	Pyrogen Study - Material Mediated	ISO 10993-11:2010
6	Implantation/Toxicity	ISO 10993-6 ISO 10993-11

All tests were completed with passing results.

- **Sterilization, Packaging and Shelf Life Testing**
  Sterilization validation testing of the FasTouch Absorbable Fixation System is performed to demonstrate compliance with ISO 11135-1. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- **Bench Testing**
  Bench testing included the following:
  TEST # 1: Fixation Strength Evaluation (BT-212)
  TEST# 2: Mesh compatibility and Integrity following fixation with the FasTouch Absorbable Fixation System (BT-213)
  TEST# 3: Performance Evaluation (BT-214)
  All tests met the predefined acceptance criteria.

- **Animal Study**
  Animal Study was performed at the Institute of Animal Research in Kibbutz Lahav in Israel by several trained surgeons evaluating the subject device in comparison to the predicate and reference devices.
  The purpose of the study was to assess the functionality and usability of the FasTouch Absorbable Fixation System.
  No adverse events occurred, devices performed well without malfunction to users' satisfaction. Users were able to perform the required tasks. Histopathology evaluation was also conducted at the preset intervals up to 3 months. The test met the predefined acceptance criteria.

VIII. CONCLUSIONS

The FasTouch Absorbable Fixation System has the same intended use as the predicate device and the reference device. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.

Performance data and animal study have been provided using both the predicate and reference device as appropriate, establishing that the FasTouch Absorbable Fixation System performs as intended and in a manner that is substantially equivalent to the predicate. Therefore, the device is substantially equivalent.