January 7, 2021

Via Surgical Ltd.
% Orly Maor
Company Consultant
Orly Maor
25A Sirkin Street
Kfar Saba, 4442156
Israel

Re: K203117
Trade/Device Name: TissueTak device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW,
Dated: October 10, 2020
Received: October 16, 2020

Dear Mr. Maor:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203117

Device Name
TissueTak device

Indications for Use *(Describe)*
The TissueTak device is intended for fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures such as hernia or rotator cuff 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.

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510(k) SUMMARY

Via Surgical Ltd.
TissueTak device
K203117

Contact Person
Orly Maor
25A Sirkin Street
Kfar Saba 44421, Israel
Tel: +972-9-7453607
Fax: +972-153-9-7453607
oram.ma@gmail.com
Date Prepared: January 5, 2021

Manufacturer
Via Surgical Ltd.
Mitzpe Kineret Street 22/1
Amirim 2011500, Israel
Tel: +972-52-639-5765
Contact Person: Ofek Levin

Subject Device
Name of Device- TissueTak device
Regulation Number- 21 CFR 878.4750
Regulation Name- Implantable staple
Regulatory class- class II
Product Code- GDW
Classification Panel- General & Plastic Surgery

Predicate Device
510(k) Number- K181668
Name of Device- FasTouch Absorbable Fixation System
Regulation Number- 21 CFR 878.4750
Regulation Name- Implantable staple
Regulatory class- class II
Product Code- GDW
Classification Panel- General & Plastic Surgery

Reference Device
510(k) Number- K131637
Name of Device- Rotation Medical Soft Tissue Staple (RMST Staple)
Regulation Number- 21 CFR 878.4750
Regulation Name- Implantable staple

Regulatory class- class II
Product Code- GDW

Indications for Use
The TissueTak device is intended for fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures such as hernia or rotator cuff repairs**.**

Purpose of 510(k)
The purpose of this 510(k) is to describe the modifications made to the cleared FasTouch Absorbable Fixation System.

Description
The TissueTak device is a disposable, sterile single-use system designed to deliver absorbable fastener into tissue and prosthesis during general surgery procedures such as hernia or rotator cuff repairs.

The Via Surgical TissueTak device, 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 TissueTak firing mechanism, thus forming a closed locked loop into the tissue affixing the surgical mesh/patch to the tissue. The fasteners are absorbable and made of PURASORB PLG 8218 dye with D&C violet No. 2.

The only change in the TissueTak device from the cleared FasTouch Absorbable Fixation System include clarification of the intended use wording to include rotator cuff repair.

Substantial Equivalence Discussion
The TissueTak device has the same intended use and indications for use, and similar principles of operation, and technological characteristics as the cleared device. The minor differences in the intended use words do not raise any new questions of safety or effectiveness. Performance data demonstrated that the modified TissueTak is as safe and effective as its predicate device. Thus, the modified TissueTak device is substantially equivalent to its predicate device.

An SE Table is presented below:

	FasTouch Absorbable Fixation System	TissueTak device	**SE**
510(k) Number	K181668	K203117	
Manufacturer	Via Surgical Ltd.	Via Surgical Ltd.	Same
Product Code	GDW	GDW	Same
CFR	878.4750	878.4750	Same

	FasTouch Absorbable Fixation System	TissueTak device	**SE**
Intended Use & Indications for Use	The FasTouch Absorbable Fixation Device is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.	The TissueTak device is intended for fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures such as hernia or rotator cuff repairs.	Same The addition of the rotator cuff as explanation of the word "various" does not change the intended use nor impact safety or effectiveness.
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
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)	PLGA8218 dyed with D&C 2 colorant 0.05% (a copolymer of L-lactide and Glycolide in a 82/18 molar ratio)	Same
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

	FasTouch Absorbable Fixation System	TissueTak device	**SE**
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

Performance Data

Performance test was conducted in order to demonstrate that the fixation strength of the modified TissueTak device have equivalent performance to the FasTouch Absorbable Fixation System predicate and its refence device.

Risk analysis was performed and it was concluded that no additional risks were raised.
In all instances, the modified TissueTak device functioned as intended and demonstrated equivalent performance to its predicate.

Conclusions

The TissueTak device is substantially equivalent to the predicate device.