DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 14, 2016

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

Re: K162252
Trade/Device Name: Fastouch™ Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 20, 2016
Received: October 21, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162252

Device Name
FasTouch™ Fixation System

Indications for Use *(Describe)*
The FasTouch™ 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.

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510(k) SUMMARY
ViaSurgical's FasTouch™ Fixation System

I. SUBMITTER

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Date Prepared: August 6, 2016

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II. DEVICE

Name of Device:	FasTouch™ Fixation System
Common or Usual Name:	FasTouch™ Fixation System
Classification Name:	Staple Implantable (21 CFR 878.4750)
Regulatory Class:	II
Product Code:	GDW
Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

The predicate device is the FasTouch™ Fixation System, cleared under K132698.

IV. DEVICE DESCRIPTION

The FasTouch™ Fixation System is a manual laparoscopic surgical instrument which is intended to facilitate hernia mesh delivery and placement in laparoscopic or open ventral hernia repair. The FasTouch™ Fixation System is disposable, single-use system designed to deliver a permanent fastener into tissue or prosthesis during general surgery procedures such as hernia repair.

The Via Surgical's FasTouch™ Fixation System is designed to be inserted through a laparoscopic port sleeve. The FasTouch™ Fixation System is packaged in its unloaded state and contains a handle and a cartridge.

The FasTouch™ Fixation System is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate device.

V. INDICATIONS FOR USE

The FasTouch™ 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 modified FasTouch™ Fixation System has the same intended use, principles of operation, and technological characteristics as the cleared FasTouch™ Fixation System. The minor differences in the handle design and in the clip do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified FasTouch™ Fixation System is as safe and effective as the FasTouch™ Fixation System. Thus, the FasTouch™ Fixation System is substantially equivalent to its predicate device.

VII. PERFORMANCE DATA

The following tests were performed and are the same as those performed and submitted in the original submission using the same acceptance criteria:

- Risk analysis per ISO 14971:2012
- Performance Evaluation (BT-114)
- Device Cartridge loading and replacement (BT-111)
- Fixation strength evaluation (BT – 112)
- Mesh compatibility and Integrity following fixation with the FasTouch Device (BT-113)
- Usability/Clinical Utility testing BT-WWH16

VIII. CONCLUSIONS

The modified FasTouch™ Fixation System device has the same intended use compared to the predicate device. The principal features of the device that were described show that the minor differences in device characteristics between the subject and predicate device do not raise any new questions of safety and effectiveness.

Performance data has been provided, establishing that the FasTouch™ Fixation System device performs as intended and in a manner that is substantially equivalent to the predicate. Therefore, the device may be found substantially equivalent.