February 28, 2023

Vascular Graft Solutions, Ltd.
c/o Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market St. 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K230248
Trade/Device Name: Viola
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 30, 2023
Received: January 30, 2023

Dear Janice Hogan:

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,

Rohini Retarekar -S

for Katherine Trivedi
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230248

Device Name
VIOLA

Indications for Use *(Describe)*
VIOLA clampless proximal anastomosis sealing system is indicated for use by cardiac surgeons during coronary artery bypass grafting procedures to maintain hemostasis and facilitate the completion of proximal anastomoses to the aorta without application of an aortic clamp.

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.

510(k) SUMMARY

Vascular Graft Solutions, Ltd.'s VIOLA

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Vascular Graft Solutions, Ltd.
24 Raoul Wallenberg Street
Tel-Aviv, Israel 6971921
Phone: +972-54-3073050
Facsimile: +972-3-6024966

Contact Person: Orit Yarden
Date Prepared: 30 January 2023

Name of Device

VIOLA

Common or Usual Name

Vascular Clamp

Classification

21 CFR 870.4450, Class II, Product Code DXC

Predicate Device

Vascular Graft Solutions, Ltd.'s VIOLA (K203307)

Intended Use / Indications for Use

VIOLA clampless proximal anastomosis sealing system is indicated for use by cardiac surgeons during coronary artery bypass grafting procedures to maintain hemostasis and facilitate the completion of proximal anastomoses to the aorta without application of an aortic clamp.

Device Description

The VIOLA is a sterile, single-use device designed to maintain hemostasis and facilitate the completion of multiple proximal anastomoses during a coronary artery bypass grafting procedure, without application of an aortic clamp. The VIOLA system can be used to create up to 4 anastomoses within the same patient.

This modified version of VIOLA includes an ergonomic handle with operating button and a straight distal end.

The VIOLA is comprised of:

1. A concentric 4 mm aortic punch with a detachable handle.
2. A sealing assembly comprising of a sealing element (which is available in two diameters), a catheter, fixation strap and a handle.
3. A silicone boundary marker stencil for marking the maximal suture line around the aortic incision.

The steps to create a sealed anastomosis hole that enables the surgeon to perform a clampless anastomosis include (1) the creation of a small "needle hole" (performed in the center of the boundary marker), (2) insertion and deployment of the sealing element, (3) creation of an anastomosis hole using the VIOLA's punch, and (4) performing the anastomosis.

Performance Data

A risk analysis was performed using the Failure Mode Effect and Criticality Analysis (FMECA) method to assess the impact of the changes. The risk analysis determined the following design verification tests were necessary to repeat: Bond Strength Testing and Simulated Use Testing. These tests passed successfully all acceptance criteria.

Substantial Equivalence

The modified VIOLA has the same intended use, indications for use, and principles of operation, and similar technological characteristics, as the predicate VIOLA (K203307). The minor differences in the modified VIOLA's technological characteristics do not raise different questions of safety or effectiveness. Performance data demonstrates that the modified VIOLA is as safe and effective as the predicate VIOLA.

Conclusions

The VIOLA is substantially equivalent to its predicate device.