February 16, 2024

Laminate Medical Technologies Ltd.
Orit Yarden
VP Clinical & Regulatory Affairs
24 Raoul Wallenberg
Tel Aviv, 6971921
Israel

Re: K240119
Trade/Device Name: VasQ
Regulation Number: 21 CFR 870.4600
Regulation Name: Extravascular support for an arteriovenous fistula for vascular access
Regulatory Class: Class II
Product Code: QVQ
Dated: January 16, 2024
Received: January 16, 2024

Dear Orit Yarden:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Carmen Gacchina Johnson, PhD
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

Enclosure

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)*
K240119

Device Name
VasQ

Indications for Use *(Describe)*
VasQ is intended for use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular 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.

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510(k) SUMMARY

Laminate Medical Technologies, VasQ

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

Laminate Medical Technologies Ltd.
24 Raoul Wallenberg
Tel Aviv, 6971921, Israel

Phone: +972-3-6344246
Facsimile: +972-3-5561746

Contact Person: Orit Yarden

Date Prepared: February 16, 2024

Name of Device

VasQ

Common or Usual Name

Extravascular support for an arteriovenous fistula for vascular access

Classification

21 CFR 870.4600, Class II, Product code QVQ

Predicate Device

Laminate Medical Technologies Ltd, VasQ (DEN220026)

Intended Use

VasQ is intended for use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery.

Device Description

VasQ is designed for use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery. The design of the device is intended to promote outward remodeling of the AVF vein and ultimate usability of the fistula by aiding in the maintenance of optimal hemodynamic flow profile and relieving excessive mechanical stress at the anastomotic connection. Implantation of the device does not interfere with the standard surgical techniques required to create the AVF (i.e. dissection, mobilization and suturing the anastomosis).

Technological Characteristics

VasQ is made entirely of nitinol and comprises two welded components. The braid is woven nitinol mesh that provides structural support to the segment of the vein that must be mobilized from its natural supporting tissue to allow surgical anastomosis to the artery. The brace is a laser cut nitinol structure intended to maintain geometric properties at the juxta-anastomosis region, designed to optimize the hemodynamic profile as flow transitions from the artery to the vein. VasQ is supplied sterile and implanted over the end-to-side AVF

anastomosis during the surgical AVF creation procedure. VasQ is supplied in a range of six dimensional models (VasQ models 1, 2, 3, 4, 5, 6) to support a range of artery and vein diameters 2mm – 6mm.
The subject VasQ device includes an additional braiding contractor and manufacturing changes for the braid component.

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: Biocompatibility, including implantation; Device integrity; Kink; Crush; corrosion.

Substantial Equivalence

The modified VasQ has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate VasQ. The minor differences in the braiding contractor do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified VasQ is as safe and effective as the predicate VasQ. Thus, the Modified VasQ is substantially equivalent to its predicate devices.

Conclusions

VasQ is substantially equivalent to the predicate device.