September 26, 2023

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

Re: DEN220026
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: April 29, 2022
Received: April 29, 2022

Dear Orit Yarden:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the VasQ, a prescription device under 21 CFR Part 801.109 with the following indications for use:

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

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the VasQ, and substantially equivalent devices of this generic type, into Class II under the generic name extravascular support for an arteriovenous fistula for vascular access.

FDA identifies this generic type of device as:

> **Extravascular support for an arteriovenous fistula for vascular access**. This device is a permanent implant which is surgically placed outside and/or around an artery and/or vein to provide external support to arteriovenous fistulas created for vascular access by means of vascular surgery.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 29, 2022, FDA received your De Novo requesting classification of the VasQ. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the VasQ into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the VasQ can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Vascular or tissue injury or bleeding	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Adverse effect of hemodynamics of the AVF	Clinical performance testing Animal performance testing
Failure to support a durable fistula that is usable for vascular access	Clinical performance testing Animal performance testing
Use of the device adversely impacts future vascular access sites	Clinical performance testing Labeling
Mechanical device failure/malfunction leading to injury or fistula failure	Clinical performance testing Non-clinical performance testing Labeling
Improper size selection	Labeling
Improper device placement	Labeling
Imaging incompatibility	Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the Extravascular support for an arteriovenous fistula for vascular access is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate:

(i) The ability to safely implant the device;
(ii) The ability of the arteriovenous fistula supported by the device to attain a blood flow rate and diameter suitable for hemodialysis;
(iii) The ability of the fistula to be used for vascular access;
(iv) The primary, assisted primary, and secondary patency of the fistula;
(v) The rates and types of device integrity events and any associated clinical sequelae;
(vi) The rates and types of all adverse events; and
(vii) The rates and outcomes of reinterventions.

(2) If FDA determines that premarket clinical information is insufficient to evaluate long-term safety and effectiveness of the product, postmarket data must be collected through an adequately designed and powered postmarket study to assess the following:
(i) The functionality and patency of the fistula through a clinically meaningful timeframe;
(ii) The rates and types of access-related, reintervention-related, and cannulation-related adverse events; and
(iii) The reasons for, rates, types, and outcomes of reinterventions.

(3) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:
(i) Implantation of the device;
(ii) Patency of the fistula; and
(iii) Gross pathology and histopathology assessing vascular injury and downstream embolization.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
(i) Resistance to kinking;
(ii) Resistance to crush and local compression;
(iii) Tensile strength of joints and components;
(iv) Device integrity;
(v) Corrosion resistance; and
(vi) Characterization and verification of all dimensions.

(5) Non-clinical testing must evaluate the compatibility of the device in a magnetic resonance (MR) environment.

(6) All patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate sterility of the device components intended to be provided sterile.

(8) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling for the device must include:
(i) Specific instructions regarding device size selection and device placement;
(ii) Expertise needed for safe use of the device;

(iii) A detailed summary of the clinical testing conducted and the patient population studied, including information on effectiveness and device- and procedure-related complications;
(iv) A detailed summary of the device technical parameters;
(v) A shelf life and storage conditions; and
(vi) MR information.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Extravascular support for an arteriovenous fistula for vascular access they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Nicole Schiavone at 240-402-4053.

Sincerely,

Nicole G. Ibrahim -S

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health