May 1, 2024

Marizyme
% John J. Smith, MD, J.D., Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Re: K240925
Trade/Device Name: DuraGraft Vascular Conduit Solution
Regulation Number: 21 CFR§ 876.4100
Regulation Name: Flushing and Storage Solution for Vascular Autografts at Room Temperature During Coronary Artery Bypass Graft Surgeries
Regulatory Class: II
Product Code: QEJ
Dated: April 4, 2024
Received: April 4, 2024

Dear John J. Smith:

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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K24925

Device Name

DuraGraft Vascular Conduit Solution

Indications for Use *(Describe)*

DuraGraft Vascular Conduit Solution is a solution indicated for adult patients undergoing Coronary Artery Bypass Grafting Surgeries and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to 4 hours.

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

Marizyme, Inc.'s DuraGraft Vascular Conduit Solution

K240925

Submitter

Marizyme, Inc
555 Heritage Dr.
Suite 205
Jupiter, FL 33458
Phone: 215-896-4403

Contact Person: Dr. Catherine J. Pachuk

Date Prepared: April 4, 2024

Trade Name of Device: DuraGraft Vascular Conduit Solution

Common Name of Device: Vascular Conduit Solution

Classification Name: Flushing Solution For Short Term Storage Of Veins At Room Temperature During Coronary Artery Bypass Graft Surgeries

Regulatory Class: Class II

Regulation: 21 CFR 876.4100

Product Code: QEJ

Predicate Device: DuraGraft Vascular Conduit Solution (DEN230002)

Device Description

DuraGraft Vascular Conduit Solution is a single-use, clear, colorless to slightly yellow, non-pyrogenic solution used as a flushing and storage solution during the harvesting and grafting interval in Coronary Artery Bypass Grafting (CABG surgeries). All ingredients are Generally Recognized as Safe (GRAS) and comply with United States Pharmacopoeia (USP) or National Formulary (NF) specifications. No components are of animal or blood origin. The product is aseptically processed using aseptic filling procedures. Stability testing at 25^{o}C supports a shelf life of 2 years at a storage temperature of 20-25^{o}C (controlled room temperature).

The salts in DuraGraft are intended for buffering (to maintain pH) and to maintain both ionic balance and isotonicity with respect to vascular conduits. The organic components are intended to provide a non-oxidizing environment for vascular conduits and to maintain additional buffering capability and osmolality. The organic components are all normal constituents of blood and are included for their roles in maintaining the extracellular environment of vascular conduits to prevent ischemic injury.

DuraGraft Vascular Conduit Solution is provided in two aseptically processed containers; Solution A and Solution B. Solution A is an aqueous based solution provided in sterile PETG bottles with white HDPE closures. Solution B is an aqueous based solution provided in sterile Type I borosilicate glass vials with bromobutyl rubber stoppers with aluminum crimps. Solution A and Solution B are mixed at the point of use to generate DuraGraft Vascular Conduit Solution which is the graft storage and flushing solution.

The mixed solution is used at room temperature and has an osmolality of about 305 Osmol/kg, viscosity of 1.06 cST, a sodium concentration of 155-160 mEq/L (sodium concentration is expressed as a range due to the use of Sodium bicarbonate for pH adjustment of Solution A and is based on review of several (10+) manufacturing batch records), and a potassium concentration of 5.8 mEq/L, and a pH of 7.4 at room temperature.

Indications for Use

DuraGraft Vascular Conduit Solution is a solution indicated for adult patients undergoing Coronary Artery Bypass Grafting Surgeries and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to 4 hours.

Substantial Equivalence

The purpose of this Special 510(k) submission was to update the storage condition and shelf life to 20-25°C (controlled room temperature) for 2 years. All other technological characteristics of the subject and predicate DuraGraft are identical. A comparison chart between the predicate and subject devices is presented below.

	DuraGraft Subject Device	**DuraGraft Predicate Device (DEN230002)**
Indications for Use	DuraGraft Vascular Conduit Solution is indicated for adult patients undergoing Coronary Artery Bypass Grafting Surgeries and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to four hours	DuraGraft Vascular Conduit Solution is indicated for adult patients undergoing Coronary Artery Bypass Grafting Surgeries and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to four hours
Major Components	Solution A Solution B	Solution A Solution B
Sterilization	Aseptically Processed (SAL 10^{-3})	Aseptically Processed (SAL 10^{-3})
Standards with which the Device Complies	ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials ISO 13408-1 Second edition 2008-06-15 Aseptic processing of health care products - Part 1: General requirements [Including: Amendment 1 (2013)]	ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials ISO 13408-1 Second edition 2008-06-15 Aseptic processing of health care products - Part 1: General requirements [Including: Amendment 1 (2013)]

	DuraGraft Subject Device	DuraGraft Predicate Device (DEN230002)
	ISO 13408-2 Second edition 2018-01 Aseptic processing of health care products - Part 2: Sterilizing filtration ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process ASTM D4169-16 Standard practice for performance testing of shipping containers and systems.	ISO 13408-2 Second edition 2018-01 Aseptic processing of health care products - Part 2: Sterilizing filtration ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process ASTM D4169-16 Standard practice for performance testing of shipping containers and systems.
Storage Temperature	20-25^{o}C	2-8^{o}C
Shelf Life	2 years	3 years

Performance Data

Long-term stability testing was performed at 25^{o}C to support the updated storage temperature and shelf life. Testing included evaluation of chemical stability, sterility endotoxin levels, and container/closure integrity and shipping package integrity. Testing met all specified criteria. Previously performed non-clinical and clinical data from DEN230002 remain applicable to the subject device.

Conclusions

DuraGraft (subject device) has the same indications for use as DuraGraft (predicate device). The composition, technological characteristics, and principles of operation are identical between DuraGraft and its predicate. Thus, the DuraGraft is substantially equivalent.