April 27, 2026

Maquet Cardiovascular, LLC
Suwah Amara
Sr. Regulatory Affairs Specialist
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K252445
Trade/Device Name: Fusion Bioline Vascular Graft (Various model numbers)
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY, DYF
Dated: March 20, 2026
Received: March 20, 2026

Dear Suwah Amara:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Ph.D.
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)*
K252445

Device Name
Fusion Bioline Vascular Graft

Indications for Use *(Describe)*
The Fusion Bioline Vascular Grafts are designed to repair or replace peripheral arteries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

(in accordance with 21 CFR part 807.92)

510(K) Number: K252445

Submitter Name and Address: Maquet Cardiovascular, LLC
45 Barbour Pond Rd
Wayne NJ 07470
United States

Contact Person: Suwah Amara
Sr. Regulatory Affairs Specialist
Tel.: (973)-692-5496
Email: suwah.amara@getinge.com

Date Prepared: April 24, 2026

Device Information

Device Trade Name: Fusion Bioline Vascular Graft

Common/Generic Name (s): Vascular Graft

Classification Name: Prosthesis, Vascular Graft, of 6mm and Greater Diameter
Prosthesis, Vascular Graft, of Less Than 6mm Diameter

Regulation Number: 870.3450

Product Code: DSY, DYF

Device Class: Class II according to 21 CFR 870.3450

Legally Marketed Predicate Device(s)	510(k) Number	Product Code
Fusion Bioline Vascular Graft	K131778	DSY

Device Description:

The Fusion Bioline Vascular Grafts are single-use, permanent implantable devices that restore blood flow by repairing or replacing peripheral arteries. They are synthetic vascular grafts constructed of two layers. The inner layer is comprised of extruded, expanded polytetrafluoroethylene (ePTFE). The outer layer is comprised of knit polyester (PET or Polyethylene Terephtalate) textile. These two layers are fused together with a proprietary polycarbonate – urethane adhesive. Externally Supported Fusion Bioline Vascular Grafts have a removable, continuous spiral support coil. The graft features a Guideline stripe to facilitate proper graft alignment. The Fusion Bioline Vascular Grafts include medicinal and recombinant products.

The Fusion Bioline Vascular Graft features a heparin and albumin coating on the graft's luminal surface. The heparin is of porcine origin and the albumin is animal-free recombinant human albumin.

Indications for Use:

The Fusion Bioline Vascular Grafts are designed to repair or replace peripheral arteries.

Indications for Use Comparison:

The subject Fusion Bioline Vascular Grafts share the same Indications For Use as the predicate device of the same name.

Comparison of Technological Characteristics with the Predicate Device:

The subject device, Fusion Bioline Vascular Grafts, and the predicate device have the following similarities:

- The same Indications for Use
- The same operating principles
- The same design (two layer graft, with the layers fused together by an adhesive., and Bioline Coating on the surface of the graft inner layer)
- The same Bioline Coating applied on the surface of the inner layer
- The same sterilization method
- The same sterile barrier packaging material and process
- The same shelf-life
- The same patient population
- The same user population
- The same anatomical site
- The same use environment

The subject device incorporates the following modifications:

- Comparable outer layer
- Comparable adhesive that fuse the outer and inner layers

Design verification and validation tests results demonstrated that the subject Fusion Bioline Vascular Graft do not raise new or different concerns of safety or effectiveness. The tests conducted to support this conclusion are included in the submission and are summarized below.

Non-Clinical and/or Clinical Test Summary:

Non-clinical performance test, design validation (user evaluation), and biocompatibility tests were conducted on the subject device to support a determination of substantial equivalence. Non-clinical performance tests were also performed to establish shelf-life; these tests are marked with an asterisk "*". There were no animal or clinical studies of the modified device.

Performance Tests

- Bond Adhesive Strength*
- Longitudinal Tensile Strength (LTS)*
- Water Entry Pressure (WEP)*
- Wall Thickness*
- Suture Retention Strength – Oblique*
- Suture Retention Strength – Longitudinal*
- Kink Diameter (unsupported graft only)*
- Relaxed Internal Diameter – RID*
- Guideline*
- Radial Burst Strength (Burst Pressure)*
- Graft Profile – OD*
- Longitudinal Axial Stretch*
- Graft Appearance*
- Bead Peel Strength (Support Graft only)*

Biocompatibility Tests

- Physical and chemical information
- Cytotoxicity
- Sensitization
- Irritation
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Subacute, Subchronic, Chronic toxicity
- Implantation
- Hemocompatibility
- Genotoxicity / Carcinogenicity

User Evaluation (Design Validation)

- Cut to length
- Suturability
- Graft appearance and handling
- Use of commercially available sheath tunneler

Conclusion:

The subject Fusion Bioline Vascular Graft and its predicate device have the same indication for use and device design. There are no performance or functional differences between the predicate and subject device. The difference between the subject device and the predicate device do not raise new or different questions of safety or effectiveness. The subject device test results demonstrate substantial equivalence to the predicate device.