



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 16, 2016

Maquet Cardiovascular, LLC  
Mark Dinger  
Sr. Regulatory Affairs Specialist  
45 Barbour Pond Drive  
Wayne, NJ 07470

Re: K153523  
Trade/Device Name: FUSION Vascular Graft  
Regulation Number: 21 CFR 870.3450  
Regulation Name: Vascular Graft Prosthesis  
Regulatory Class: Class II  
Product Code: DSY  
Dated: December 1, 2015  
Received: December 9, 2015

Dear Mark Dinger:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153523

Device Name

FUSION Vascular Grafts

Indications for Use (Describe)

FUSION Vascular Grafts are designed to repair or replace peripheral arteries and to provide vascular access.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**FUSION Vascular Graft AV Access Indication**

**510(k) Summary**

Prepared in accordance with 21 CFR Part 807.92

**510(k) Number:** K153523

**Date Prepared:** 1 December 2015

**Device Owner:** MAQUET Cardiovascular LLC  
45 Barbour Pond Drive  
Wayne, New Jersey 07470

**Contact Personnel:** Mark Dinger  
**Title:** Sr. Regulatory Affairs Specialist  
**Email:** [mark.dinger@maquet.com](mailto:mark.dinger@maquet.com)  
**Phone:** 973-709-7691 **Fax:** 973-909-9954

**Trade Name:** FUSION Vascular Grafts

**Device Generic Name:** Vascular Graft

**Classification:** According to 21 CFR 870.3450 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Product code DSY.

**Predicate Devices:** K131778 FUSION Vascular Grafts  
(SE: 14 November 2013)  
K962433 EXXCEL ePTFE Vascular Graft  
(SE: 1 April 1997)

**Device Description:** FUSION Vascular Grafts 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 textile. These two layers are fused together with a proprietary polycarbonate – urethane adhesive.

**Indications for Use:** FUSION Vascular Grafts are designed to repair or replace peripheral arteries and to provide vascular access.

**Technological Characteristics**

The Proposed FUSION and the predicate FUSION device have the following similarities:

- the same operating principles,
- incorporate the same basic design,
- sterilized using the same materials and processes,
- has same packaging,
- the same biocompatibility.

The Proposed FUSION and the predicate FUSION devices have the following differences:

- Vascular Access Indication for Use

The Proposed FUSION Vascular Graft and the predicate EXXCEL ePTFE Vascular Graft have the similar Vascular Access Indication and share the same substrate.

The difference is not considered a technological difference and is substantially equivalent to the predicate devices.

**Safety and Performance:**

MAQUET Cardiovascular's development process required that the following activity be:

- Performance testing - Burst After Repeated Puncture

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed FUSION Vascular Graft.

**Conclusion:**

Based on the technological characteristics and performance testing, the FUSION Vascular Grafts have been shown to be substantially equivalent to the predicate device for the intended use.