

510(k) Summary
(as required by 21 CFR 807.92)

510(k) Number: K131778

Date Prepared: September 12, 2013

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

NOV 14 2013

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Trade Name: FUSION™ and FUSION™ Bioline Vascular Grafts

Common Name: Vascular Graft

Classification Name: Vascular Graft Prosthesis

Predicate Device: EXXCEL™ Soft ePTFE Vascular Grafts (K962433, K052964 and K113101)

Device Description: FUSION™ Vascular Grafts are synthetic vascular grafts constructed of two layers. The inner layer is comprised of expanded polytetrafluoroethylene (ePTFE). The outer layer is comprised of knitted polyester textile. These two layers are bonded together. The FUSION™ Bioline Vascular Grafts have a heparin/albumin coating on the interior surface of the graft.

Indications for Use: FUSION™ and FUSION™ Bioline Vascular Grafts are designed to repair or replace peripheral arteries.

Technological Characteristics Safety and Performance: Bench testing, biocompatibility, animal and clinical testing were performed to support a determination of substantial equivalence.
Bench testing performed:

- Longitudinal Tensile Strength
- Wall Thickness
- Oblique Suture Retention Strength
- Longitudinal Suture Retention Strength
- Kink Diameter
- Relaxed Internal Diameter
- Longitudinal Axial Stretch
- Water Entry Pressure (WEP)
- Radial Burst Strength (Burst Pressure)
- Usable Length
- Shear Bond Strength

Also for products with external support (supported):

- Bead Peel Strength
- Bead Wrap Density
- Crush Resistance

For FUSION Bioline, grafts were additionally tested for:
Heparin concentration.

Animal studies:

The FUSION/FUSION Bioline Vascular Grafts were tested in two animal models.

In vivo canine and porcine implant studies were performed to assess device safety by evaluating vascular compatibility. The canine study was designed to address tissue response and patency. The model used for the canine study was a femoral arteriovenous shunt; the study compared the FUSION Vascular Graft with Exxcels Soft Vascular Graft.

- Patency was comparable for the FUSION Vascular Graft and Exxcels Soft Grafts.
- The healing process of the FUSION Vascular Graft was comparable with the Exxcels Soft Graft. Both Grafts demonstrated a benign healing response with no evidence of safety concerns.

The porcine study compared FUSION to FUSION Bioline and FUSION Bioline to GORE PROPATEN in a porcine carotid model. FUSION to FUSION Bioline were compared for comparable surfaces and expected clinical hemocompatibility. The surfaces were found to be comparable as well as comparable to Exxcels. FUSION Bioline was compared to GORE PROPATEN for patency and tissue response. The grafts remained widely patent in both groups and tissue response was similar.

Clinical Studies:

Randomized Multicenter Trial of FUSION Bioline Graft for Femoropopliteal Bypass

Methods: Prospective, randomized, multicenter trial performed to evaluate the safety and efficacy of FUSION Bioline Vascular Graft to demonstrate substantial equivalence with EXXCEL Soft ePTFE. Eighteen US and 7 European centers enrolled 207 subjects with Rutherford 1-5 chronic limb ischemia and planned prosthetic femoropopliteal (above- and below-knee) bypass. Subjects were randomized 1:1 to either FUSION-Bioline or EXXCEL Soft ePTFE. Patency was assessed by vascular imaging and ABI. Early (6 month) results were analyzed for primary graft patency and major adverse limb events (MALE).

Efficacy Endpoints: Primary efficacy endpoint was primary patency of the graft at 6 months. Secondary endpoints were primary assisted patency, secondary patency, and time to hemostasis of suture hole bleeding.

Safety Endpoints: Composite MALE (major reintervention rates, major amputation rates) and periprocedural deaths at 6 months.

Results: Primary patency at 6 months was 86.4% for FUSION Bioline compared to 70.0% for the EXXCEL group. The difference was 16.4% with a non-inferiority p-value of <0.0001. Primary-assisted patency rate for FUSION Bioline was 86.4% vs. 73.0% for EXXCEL (p=0.0174). Secondary patency rates at 6 months did not reach significance with 88.3% for FUSION Bioline vs. 80.8% for EXXCEL (p=0.1371). MALE occurred in 14.3% (15/105) for FUSION Bioline and 29.7% (30/101) for EXXCEL at 6 Months (P=0.0109). No perioperative deaths occurred in either group. Suture-hole bleeding times were significantly shorter with FUSION Bioline (p<0.0001); observed mean times to hemostasis were 3.5 ±4.7 minutes for FUSION Bioline vs. 11.0 ±10.6 minutes for the EXXCEL group.

European Postmarketing Trial of FUSION Graft for Femoropopliteal Bypass

Methods: Prospective, single-arm multicenter, trial performed to evaluate the safety and efficacy of FUSION vascular graft. Ten European study centers enrolled 117 subjects with peripheral artery disease scheduled for above-knee bypass. Eligible subjects received the FUSION graft. Patency was assessed by vascular imaging and ABI. Twelve-month results were analyzed for primary graft patency and major adverse limb events (MALE): major reintervention rates, major amputation rates, and perioperative deaths.

Endpoints: Primary efficacy endpoint was primary patency of the FUSION graft at 12 months. Primary safety endpoint was the assessment of composite major adverse limb events (MALE) and periprocedural deaths.

Results: Preliminary 12-month results submitted for the 510(k) provided endpoint results in 92 subjects. Primary patency rate at 12 months was 84.8% (78/92) and the observed secondary patency was 95.4% (83/87). Thirteen (11.2%) subjects had major adverse limb events. No periprocedural deaths.

The results of these tests provide reasonable assurance that the device(s) have been designed and tested to assure conformance to the performance specifications, perform as intended and are safe and effective. The test data provided in the submission supplies evidence that the device(s) are substantially equivalent to

the predicate device. No new safety or performance issues were raised during the testing regimen.

Conclusion:

Based on the Indications for Use, technological characteristics, safety and performance testing, the FUSION™ and FUSION™ Bioline Vascular Grafts have been shown to be safe and effective for their intended use and substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

November 14, 2013

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

MAQUET Cardiovascular LLC
C/O Marylou Insinga
Regulatory Affairs Specialist II
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K131778
Trade/Device Name: FUSION™ and FUSION™ Bioline Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: November 1, 2013
Received: November 4, 2013

Dear Ms. Insinga:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

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

Indications for Use

510(k) Number (if known): K131778

Device Name: FUSION™ and FUSION™ Bioline Vascular Grafts

Indications For Use:

FUSION™ and FUSION™ Bioline Vascular Grafts are designed to repair or replace peripheral arteries.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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