510(k) Summary: K140789

JUL 15 2014

Company Information

Company Name:	CorMatrix Cardiovascular, Inc.
Contact Name:	Bryan Brosseau
Contact Title:	Regulatory Affairs Manager
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Date Prepared:	April 15, 2014

Product Information

Trade Name:	CorMatrix® ECM® for Vascular Repair
Common Name:	Patch, Pledget and Intracardiac
Classification Name:	Patch, Pledget and Intracardiac, 21 CFR 870.3470 Product Code DXZ, Class II

Predicate Devices

The CorMatrix® ECM® for Vascular Repair is substantially equivalent to the following devices:

- Synovis® Vascu-Guard® Peripheral Vascular Patch, K983602
- CorMatrix ECM for Carotid Repair, K111187
- Cook® Biotech Surgisis® Peripheral Vascular Patch, K001785
- CorMatrix ECM for Cardiac Tissue Repair, K063349

Indications for Use

The CorMatrix® ECM® for Vascular Repair is intended for use as a patch material for repair and reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral, and tibial blood vessels. The CorMatrix ECM for Vascular Repair may be used for patch closure of vessels, as a pledget, or for suture line buttressing when repairing peripheral vessels.

Device Description

The CorMatrix ECM for Vascular Repair is an extracellular matrix (ECM) scaffold derived from porcine small intestinal submucosa (SIS). The device is constructed of a multilaminate (6-ply), decellularized, non-crosslinked, lyophilized ECM cut to specific shapes and sizes and terminally sterilized using Ethylene Oxide gas.

The 6-ply CorMatrix ECM for Vascular Repair is derived from the same multilaminate SIS-ECM material as the CorMatrix ECM for Carotid Repair (6-ply), the Cook Biotech Surgisis Peripheral Vascular Patch (4-ply), and the CorMatrix ECM for Cardiac Tissue Repair (4-ply). The CorMatrix

ECM for Vascular Repair will be supplied as a 6-ply, lyophilized, sterilized sheet of SIS-ECM. The device design, construction, and configurations are identical to the FDA-cleared CorMatrix ECM for Carotid Repair (K111187).

Non-Clinical Testing Summary

All non-clinical testing performed for the CorMatrix ECM for Carotid Repair (K111187) supports the CorMatrix ECM for Vascular Repair as the device materials are identical. The criteria established for suture retention strength, probe burst strength, and tensile strength for the carotid artery application are also relevant to the expanded indications as carotid repair represents the most challenging application associated with the expanded indications.

The animal testing performed for the CorMatrix ECM for Carotid Repair (K111187) demonstrates that the device performs as intended with no systemic or local adverse events. The device testing demonstrated that the device exhibited less angiographic stenosis, better tissue integration, less calcification, and greater re-endothelialization than the control device. The performance of the device when used for carotid repair in the animal model supports the use of the 4-ply ECM material for the expanded Indications for Use for CorMatrix ECM for Vascular Repair.

Bench testing performed for the CorMatrix ECM for Carotid Repair (K111187) directly supports the CorMatrix ECM for Vascular Repair. Testing included evaluation of:

- Suture Retention Strength
- Probe Burst Strength
- Tensile Strength

The testing listed above demonstrates that the device will perform as intended for the proposed Indications for Use. The suture retention strength, probe burst strength, and tensile strength of the device far exceed the mechanical forces experienced in the clinical setting for all of the applications proposed in the expanded Indications for Use.

The collective non-clinical data described above supports the proposed Indications for Use of the CorMatrix ECM for Vascular Repair and does not raise any new concerns of safety or effectiveness.

Substantial Equivalence

The device design, construction, and configurations are identical to the CorMatrix ECM for Carotid Repair (K111187). The proposed indications for the CorMatrix ECM for Vascular Repair are equivalent to the Indications for Use of predicate devices identified above. The Indications for Use of the CorMatrix ECM for Vascular Repair, Cook Biotech Surgisis Peripheral Vascular Patch, and the Synovis Vascu-Guard all include repair of peripheral vessels, including the carotid, renal, iliac, femoral, and tibial blood vessels.

The differences between the Indications for Use of the CorMatrix ECM for Vascular Repair when compared to the CorMatrix ECM for Carotid Repair (K111187) include only changes to the specific vessels which may be repaired with the device. The changes are minor and do not raise any new concerns associated with safety and effectiveness.

Conclusion

The CorMatrix ECM for Vascular Repair is substantially equivalent to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 15, 2014

CorMatrix Cardiovascular, Inc.
% Bryan Brosseau
Regulatory Affairs Manager
1100 Old Ellis Road
Roswell, Georgia 30076

Re: K140789
Trade/Device Name: CorMatrix® ECM® for Vascular Repair
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget Made of Polypropylene, Polyethylene Terephthalate, or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: April 15, 2014
Received: April 16, 2014

Dear Mr. Brosseau:

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" (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 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,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140789

Device Name
CorMatrix® ECM® for Vascular Repair

Indications for Use *(Describe)*
The CorMatrix® ECM® for Vascular Repair is intended for use as a patch material for repair and reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral, and tibial blood vessels. The CorMatrix ECM for Vascular Repair may be used for patch closure of vessels, as a pledget, or for suture line buttressing when repairing peripheral vessels.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kenneth J. Cavanaugh -S