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

August 15, 2014

Cormatrix Cardiovascular, Inc.
Bryan Brosseau
Regulatory Affairs Manager
1100 Old Ellis Road
Roswell, GA 30076 US

Re: K140306
Trade/Device Name: Cormatrix protect ecm envelope
Regulation Number: 21 CFR 870.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: July 15, 2014
Received: July 16, 2014

Dear Bryan 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

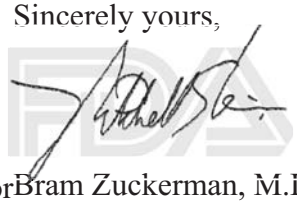
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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)*

Device Name
CorMatrix® PROTECT ECM® Envelope

Indications for Use *(Describe)*
The CorMatrix PROTECT ECM Envelope is intended to securely hold an implantable electronic device to create a stable environment when implanted in the body. The devices that may be used with the CorMatrix PROTECT ECM Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices.

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)*

510(k) Summary: K140306

Company Information

Company Name:	CorMatrix Cardiovascular, Inc.
Contact Name:	Bryan Brosseau
Contact Title:	Regulatory Affairs Manager
Address:	1100 Old Ellis Rd. Roswell, GA 30076
Phone:	470-514-4036
Fax:	408-734-2629

Date Prepared: March 18, 2014

Product Information

Trade Name:	CorMatrix® PROTECT ECM® Envelope
Common Name:	Surgical Mesh Envelope
Classification Name:	Surgical Mesh, 21 CFR 878.3300, Product Code FTM, Class II

Predicate Devices

The CorMatrix® PROTECT ECM® Envelope is substantially equivalent to the following devices:

- TyRx AIGIS$_{Rx}$ Antibacterial Envelope, K063091
- TyRx AIGIS$_{Rx}$ R Fully Resorbable Antibacterial Envelope, K130943
- CorMatrix ECM for Cardiac Tissue Repair, K063349
- Cook Biotech SurgiSIS Surgical Mesh, K980431 and K062696
- Cook Biotech Biodesign Tissue Graft, SIS Hernia Repair Device, K062697 and K073391

Device Description

The CorMatrix PROTECT ECM Envelope is intended to securely hold a cardiac implantable electronic device (CIED) in order to create a stable environment when implanted in the body. The devices that may be used with the CorMatrix PROTECT ECM Envelope include pacemaker pulse generators, defibrillators, or other CIEDs.

The CorMatrix PROTECT ECM (extracellular matrix) Envelope is constructed from two perforated, multilaminate sheets (4-ply) of decellularized, non-crosslinked, lyophilized ECM derived from porcine small intestinal submucosa. The 3 mm perforations are spaced evenly at 10 mm apart to allow exit of any exudate. The ECM is assembled into pouch form using with violet 5-0 polydioxanone (PDS) suture.

Substantial Equivalence

The intended use of the CorMatrix PROTECT ECM Envelope to securely hold a CIED is identical to the TyRx AIGIS and TyRx AIGIS R envelopes. The device is manufactured from the same or

similar materials as the CorMatrix ECM for Cardiac Tissue Repair, Cook Biotech SurgiSIS Surgical Mesh, and Cook Biotech Biodesign Tissue Graft, SIS Hernia Repair Device.

Non-clinical Testing

An animal study was performed to demonstrate the ability of the CorMatrix PROTECT ECM Envelope to isolate and stabilize a pacemaker in a model of bilateral, subcutaneous implant pockets of a New Zealand White rabbit. The CorMatrix PROTECT ECM Envelope effectively isolated and stabilized the pacemaker with biocompatibility similar to the predicate device, TyRx AIGISRx Antibacterial Envelope.

Conclusion

The CorMatrix PROTECT ECM Envelope is substantially equivalent to the predicate devices.