October 10, 2018

CorMatrix Cardiovascular, Inc.
℅ Wendy Perreault
Owner/Principal
New South Regulatory, LLC
223 Coventry Road
Decatur, Georgia 30030

Re: K181038
Trade/Device Name: CorMatrix Cor Patch (3 cm x 5 cm)(single pack), CorMatrix Cor Patch (4 cm x 7 cm)(single pack), CorMatrix Cor Patch (7 cm x 10 cm)(single pack)
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: PSQ
Dated: April 18, 2018
Received: April 19, 2018

Dear Wendy Perreault:

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. 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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181038

Device Name
CorMatrix(R) Cor Patch

Indications for Use *(Describe)*
CorMatrix(R) Cor Patch is intended for epicardial tissue support and repair.

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.

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510(k) Summary: K181038

Company Information

Company Name:	CorMatrix Cardiovascular, Inc.
Contact Name:	Wendy Perreault
Contact Title:	Regulatory Consultant
Address:	1100 Old Ellis Rd. Roswell, GA 30076
Phone (office):	678-566-2628
Phone (mobile):	404-542-5854
Fax:	678-736-5082
Date Prepared:	April 18, 2018

Product Information

Trade Name:	CorMatrix® Cor Patch
Common Name:	Patch, Pledget and Intracardiac
Classification Name:	Patch, Pledget and Intracardiac, 21 CFR 870.3470 Product Code PSQ, Class II
Classification Panel:	Cardiovascular

Predicate Devices

The CorMatrix® Cor Patch is substantially equivalent to the CorMatrix® Tyke®, K152127.

Device Description

CorMatrix Cor Patch is intended for epicardial tissue support and repair.

CorMatrix Cor Patch is derived from the same multi-laminate SIS-ECM material as the CorMatrix Tyke (2-ply, non-pressed). The CorMatrix® Cor Patch will be supplied as a 4-ply, lyophilized, sterilized sheet of SIS-ECM. With the exception of the differing layer counts and a change to the manufacturing process for the Cor Patch which does not result in a change to the fundamental technology of the device, the device design and construction are identical to the FDA-cleared CorMatrix® Tyke™ (K152127).

Indications for Use

The CorMatrix Cor Patch is intended for epicardial tissue support and repair.

Substantial Equivalence

The device is constructed from the same SIS-ECM material used for construction of the CorMatrix Tyke (K152127). The device differs from the CorMatrix Tyke only in the number of ECM layers from which

each device is constructed, and additional processing (wash) steps for the Cor Patch device which serve to further remove impurities from the SIS-ECM.

The CorMatrix Cor Patch is a four-layer ECM material, and the CorMatrix Tyke is a two-layer ECM material. The CorMatrix Tyke is intended for use in neonates and infants, and is therefore provided in a maximum size of 4 cm x 7 cm, whereas the CorMatrix Cor Patch is provided in sizes up to 7 cm x 10 cm. Each layer of the Cor Patch device is identical to the ECM layers in the predicate device, with the exception of the additional processing step performed for the Cor Patch product.

The Indications for Use for the predicate CorMatrix Tyke include use as an epicardial covering for damaged or repaired cardiac structures; the Cor Patch is intended for epicardial tissue support and repair.

Non-clinical Testing

The CorMatrix Cor Patch is intended for epicardial tissue support and repair. The performance testing that supports the Cor Patch includes tensile strength, suture retention, and burst strength testing. The testing demonstrates that the sterile SIS-ECM of the Cor Patch possesses adequate material properties for use in the indicated applications.

Conclusion

Performance testing of the SIS-ECM material of the Cor Patch demonstrated that it exceeds the biomechanical requirements for its intended use.

The CorMatrix Cor Patch is substantially equivalent to the CorMatrix Tyke; both are intended for epicardial support and repair and are made from porcine SIS-ECM. The Cor Patch undergoes an additional processing step which serves to further remove impurities from the base material, but does not result in a change to the fundamental technology of the devices.