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

February 04, 2016

CorMatrix Cardiovascular, Inc.
Mr. Andrew Green
Executive Vice President of Operations
1100 Old Ellis Road
Roswell, Georgia 30076

Re: K152127
Trade/Device Name: CorMatrix Tyke
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: January 6, 2016
Received: January 7, 2016

Dear Mr. Green:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152127

Device Name
CorMatrix® Tyke™

Indications for Use *(Describe)*

The CorMatrix® Tyke™ is intended for use in neonates and infants for repair of pericardial structures, as an epicardial covering for damaged or repaired cardiac structures, as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing, and cardiac 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.

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510(k) Summary: K152127

Company Information

Company Name:	CorMatrix Cardiovascular, Inc.
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Date Prepared: February 3, 2016

Product Information

Trade Name:	CorMatrix® Tyke™
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® Tyke™ is substantially equivalent to CorMatrix® ECM® for Cardiac Tissue Repair, K063349.

Device Description

CorMatrix® Tyke™ is intended for use in neonates and infants for repair of pericardial structures, as an epicardial covering for damaged or repaired cardiac structures, as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing, and cardiac repair.

CorMatrix® Tyke™ is derived from the same multi-laminate SIS-ECM material as the CorMatrix ECM for Cardiac Tissue Repair (4-ply). The CorMatrix® Tyke™ will be supplied as a 2-ply, lyophilized, sterilized sheet of SIS-ECM. With the exception of the differing layer counts, the device design and construction are identical to the FDA-cleared CorMatrix ECM for Cardiac Tissue Repair (K063349).

Indications for Use

The CorMatrix® Tyke™ is intended for use in neonates and infants for repair of pericardial structures, as an epicardial covering for damaged or repaired cardiac structures, as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing, and cardiac repair.

Substantial Equivalence

The device is constructed from the identical ECM material used for construction of the CorMatrix® ECM® for Cardiac Tissue Repair (K063349). The device differs from the CorMatrix® ECM® for Cardiac Tissue Repair only in the number of ECM layers from which each device is constructed.

The CorMatrix® Tyke™ is a two-layer ECM material and the CorMatrix® ECM® for Cardiac Tissue Repair is a 4-layer ECM material. Due to the handling and remodeling characteristics of the 2-ply material, the CorMatrix® Tyke™ is well-suited for pediatric, lower-pressure applications. The Indications for Use are specific for the thinner ECM material by limiting use to lower-pressure applications. Due to the pediatric populations for which the CorMatrix® Tyke™ is intended, the device is provided in a maximum size of 4 cm x 7 cm whereas the predicate device (CorMatrix® ECM® for Cardiac Tissue Repair) is provided in sizes up to 7 cm x 20 cm.

Each layer of the device is identical to the ECM layers in the predicate device. However, the 2-ply CorMatrix® Tyke™ was designed to address the needs of surgeons requesting a thinner ECM material.

The Indications for Use for the CorMatrix® Tyke™ also include pericardial closure. The CorMatrix RegeneSIS Pericardial Patch (K051405) is identical to the CorMatrix® ECM® for Cardiac Tissue Repair and was a predicate device for clearance of the CorMatrix® ECM® for Cardiac Tissue Repair.

Non-clinical Testing

The CorMatrix® Tyke™ is intended for use as a reconstructive material for the repair and reconstruction of cardiac structures, including the pericardium. The performance testing conducted for the CorMatrix® Tyke™ includes tensile strength, suture retention, and burst strength testing. The testing demonstrated that the sterile CorMatrix® Tyke™ possesses adequate material properties for use in the indicated applications. The testing demonstrates that the material withstands the tension, suture tension, and hemodynamic forces exerted on the material when used for pediatric cardiovascular repair, pericardial reconstruction, and venous cardiac outflow reconstruction.

A non-clinical investigational study was conducted to evaluate the in vivo performance of CorMatrix® Tyke™ patches. The CorMatrix Tyke (2-ply ECM material) was compared to the commercially available CorMatrix® ECM® for Cardiac Tissue Repair (4-ply ECM). Aortic and pulmonary artery implant sites were selected to correspond with the usual repair sites for which the CorMatrix® ECM® for Cardiac Tissue Repair is clinically used. Histological techniques were used to evaluate the structural integrity of both materials along with host cellular response during the remodeling process at 90 days and 180 days post-implantation.

Conclusion

Performance testing of the CorMatrix® Tyke™ (2-ply ECM material) demonstrated that it exceeds the biomechanical requirements for its intended use as well as the biomechanical

requirements of the CorMatrix® ECM® for Cardiac Tissue Repair (4-ply ECM material). The non-clinical study data demonstrated optimal healing features in both the Control (Cardiac Tissue Repair) and Test (Tyke) groups. The structural integrity of the arteriotomy sites were restored through fibrocellular integration of the ECM implant and formation of a fully mature, stable, and endothelialized neointima in both groups, and there were no adverse changes recorded.

The CorMatrix® Tyke™ is substantially equivalent to the CorMatrix® ECM® for Cardiac Tissue Repair.