510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K063349

This summary of the 510(k) premarket notification for the CorMatrix Patch for Cardiac Tissue Repair is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

510(k) SUMMARY

FEB 16 2007

510(k) Notification K063349

GENERAL INFORMATION

Applicant:
CorMatrix Cardiovascular, Inc.
155 Moffett Park Dr., Suite A-240
Sunnyvale, CA 94089-1330
Phone: (408) 734-2628
FAX: (408) 734-2629

Contact Person:
Kit Cariquitan
Regulatory Consultant
Experien Group, LLC
155 Moffett Park Drive, Suite A-101
Sunnyvale, CA 94089
Phone: 408-400-0856 (x112)
FAX: 408-400-0865
Email: kitc@experiengroup.com

Date Prepared:
January 16, 2007

DEVICE INFORMATION

Trade/Proprietary Name:
CorMatrix Patch for Cardiac Tissue Repair

Common/Classification Name/Product Code:
Product Code: DXZ
Device Classification Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulation Number: 21CFR§870.3470

Device Classification:
Class II

PREDICATE DEVICES

- Cook Biotech, Inc., SurgiSIS Surgical Mesh (K980431)
- CorMatrix Cardiovascular, Inc., CorMatrix Patch for Pericardial Closure (K051405)
- Peritec Biosciences LTD, PFA Vascular Patch (K041736)
- Shelhigh, Shelhigh *No-React* VASCUPATCH (K982810)
- Bio-Vascular, Inc., CV Peri-Guard Cardiovascular Patch (K983602)
- Synovis Surgical Innovations, Peri-Strips Staple Line Reinforcement (K040415)
- Boston Scientific Corp., PTFE Felts and Pledgets (K041716)

INTENDED USE

The CorMatrix Patch for Cardiac Tissue Repair is intended for use as an intracardiac patch or pledget for tissue repair (i.e., atrial septal defect (ASD), ventricular septal defect (VSD), etc.) and suture-line buttressing.

PRODUCT DESCRIPTION

The CorMatrix Patch for Cardiac Tissue Repair is manufactured from porcine small intestinal submucosa (SIS) and is supplied in four (4)-ply sheets with varying dimensions.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the CorMatrix Patch for Cardiac Tissue Repair are substantially equivalent to the indications for use of the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the CorMatrix Patch for Cardiac Tissue Repair is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Any differences in technological characteristics between the CorMatrix Patch for Cardiac Tissue Repair and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the SIS material used in the CorMatrix Patch for Cardiac Tissue Repair was evaluated through extensive biocompatibility, bench and animal testing. The collective results have demonstrated that the CorMatrix Patch for Cardiac Tissue Repair is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

SUMMARY

The CorMatrix Patch for Cardiac Tissue Repair is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Experien Group
c/o Mr. Kit Cariquitan, Regulatory Consultant
155 Moffett Park Drive
Suite A-101
Sunnyvale, CA 94089

FEB 16 2007

Re: K063349
Trade/Device Name: CorMatrix Patch for Cardiac Tissue Repair
Regulation Number: v21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget
Regulatory Class: Class II (two)
Product Code: DXZ
Dated: January 16, 2007
Received: January 17, 2007

Dear Mr. Cariquitan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K063349

Device Name: CorMatrix Patch for Cardiac Tissue Repair

Indications For Use: The CorMatrix® Patch for Cardiac Tissue Repair is indicated for use as an intracardiac patch or pledget for tissue repair (i.e., arterial septal defect (ASD), ventricular septal defect (VSD), etc.) and suture-line buttressing.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063349