

AUG 31 2005

**510(k) SUMMARY**

**510(k) Notification K051405**

**GENERAL INFORMATION**

**Applicant:**

CorMatrix Cardiovascular, Inc.  
919 Waverly Road  
Tallahassee, FL 32312  
Phone: 850-508-0100  
FAX: 850-383-1699

**Contact Person:**

Ms. Punam Gollamudi  
Regulatory Project Manager  
Experien Group, LLC  
155 Moffett Park Drive, Suite A-101  
Sunnyvale, CA 94089  
Phone: 408-400-0856  
FAX: 408-400-0865  
Email: punam@experiengroup.com

**Date Prepared:**

July 18, 2005

**DEVICE INFORMATION**

**Trade/Proprietary Name:**

CorMatrix Pericardial Patch

**Common/Classification Name/Product Code:**

Product Code: DXZ  
Device Classification Name: Patch, Pericardial

**Device Classification:**

Class II

**PREDICATE DEVICES**

- Cook Biotech, Inc., SurgiSIS (K980431)
- TEI Biosciences, Inc., TISSUEMEND (K020455)
- W.L. Gore & Associates, Inc., Preclude Pericardial Membrane (K012098)
- PM Devices, Inc., Peripatch Sheet (K031948)

**INTENDED USE**

The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.

**PRODUCT DESCRIPTION**

The CorMatrix Pericardial Patch 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 Pericardial Patch 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 Pericardial Patch is substantially equivalent to the predicate devices.

**TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION**

Any differences in technological characteristics between the CorMatrix Pericardial Patch 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 Pericardial Patch was evaluated through extensive biocompatibility, bench and animal testing. The collective results have demonstrated that the CorMatrix Pericardial Patch is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

**SUMMARY**

The CorMatrix Pericardial Patch is substantially equivalent to the predicate devices.



**FEB 23 2009**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

CorMatrix Cardiovascular, Inc.  
c/o Ms. Punam Gollamudi  
Regulatory Consultant  
919 Waverly Road  
Tallahassee, FL 32312

Re: K051405  
CorMatrix Pericardial Patch  
Regulation Number: 21 CFR 870.3470  
Regulation Name: Intracardiac patch or pledget  
Regulatory Class: II (two)  
Product Code: 74 DXZ  
Dated: July 18, 2005  
Received: July 19, 2005

Dear Ms. Gollamudi:

This letter corrects our substantially equivalent letter of August 31, 2005.

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 (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 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

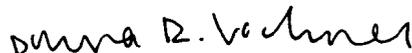
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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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/dsma/dsmamain.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): K051405

Device Name: CorMatrix Pericardial Patch

Indications For Use: The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.

Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use    
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vechner  
(Division Sign-Off)  
Division of Cardiovascular Devices

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