K131286

510(k) Summary

This 510(k) summary for PriMatrix is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by

TEI Biosciences Inc.
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AUG 0 5 2013

Contact Person

Kenneth James, Ph.D.
Vice President, Product Sciences and Regulatory Affairs

Date Prepared

April 25, 2013

Device Information

Proprietary name:	PriMatrix
Common name:	Animal-derived, dermal extracellular matrix wound care product
Classification:	Unclassified

Device Description

PriMatrix is an acellular dermal tissue matrix. The device is supplied sterile and is provided in sheet form in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs.

Intended Use

PriMatrix is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Legally Marketed Devices to which Equivalence is Being Claimed

PriMatrix is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
PriMatrix	TEI Biosciences	K083440
DressSkin	TEI Biosciences	K023778

Summary of Technological Characteristics and Biocompatibility

PriMatrix is substantially equivalent to other wound care products with respect to its design and application.

A rigorous biocompatibility assessment performed by an independent certified laboratory demonstrated the biocompatibility of PriMatrix. The tests performed included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, hemolysis, and pyrogenicity. The manufacturing methods for PriMatrix were also tested by an independent laboratory to assure safe levels of viral inactivation.

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

Tei Biosciences Incorporated
% Kenneth James, Ph.D.
Vice President, Product Science and Regulatory Affairs
7 Elkins Street
Boston, Massachusetts 02127

August 5, 2013

Re: K131286
Trade/Device Name: PriMatrix Dermal Repair Scaffold
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 25, 2013
Received: May 23, 2013

Dear Dr. James:

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" (21CFR 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 Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131286

Device Name: PriMatrix Dermal Repair Scaffold

Indications For Use:

PriMatrix is intended for the management of wounds that include:

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- Tunneled/undermined wounds
- Draining wounds

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131286