K100261

4/2

DEC 10 2010

510(k) Summary

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

Submitted by

TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127
(617) 268-1616
(617) 268-3282 (fax)

Contact Person

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

Date Prepared

September 3, 2010

Device Information

Proprietary name:	PriMatrix Ag Antimicrobial Dermal Repair Scaffold
Common name:	Animal-derived, extracellular matrix wound care product
Classification:	Unclassified

Device Description

PriMatrix Ag Antimicrobial is an acellular dermal tissue matrix derived from fetal bovine dermis. PriMatrix Ag Antimicrobial is supplied sterile in a variety of sizes that can be trimmed by the surgeon to meet the individual patient's needs. The Ionic Silver content is intended to prevent microbial colonization of the device.

Intended Use

PriMatrix Ag Antimicrobial Dermal Repair Scaffold 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-Mohs 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 Ag Antimicrobial is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
PriMatrix	TEI Biosciences	K083440
DressSkin	TEI Biosciences	K023778
ColActive Ag	Covalon Technologies	K043296
Exsalt SD7	Exciton Technologies	K083870

K100261

2/2

Summary of Technological Characteristics and Biocompatibility

PriMatrix Ag Antimicrobial 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 Ag Antimicrobial. The tests performed included: cytotoxicity, hemolysis, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation and pyrogenicity. The manufacturing methods for PriMatrix AG Antimicrobial were also tested by an independent laboratory to assure safe levels of viral inactivation.

Ionic silver is a broad spectrum antimicrobial. PriMatrix AG Antimicrobial has been shown in CLSI Disc Susceptibility testing to be effective against a range of bacteria, including: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli,* Methicillin Resistant *Staphylococcus aureus* (MRSA), *Enterococcus faecium, Klebsiella pneumonia, Serratia marcescens, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecalis* (VRE), *Acinetobacter baumanni and Streptococcis pyrogenes* (Group A). PriMatrix AG Antimicrobial has also been demonstrated, in a rodent model, to reduce levels of *Staphylococcus aureus* recovered from a contaminated wound site from ten million to no viable bacteria recovered on PriMatrix AG Antimicrobial or at the wound site within three days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TEI Biosciences Inc.
% Kenneth James, Ph.D.
7 Elkins Street
Boston, Massachusetts 02127

DEC 10 2010

Re: K100261
Trade/Device Name: PriMatrix Ag Antimicrobial Dermal Repair Scaffold
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 30, 2010
Received: December 01, 2010

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.

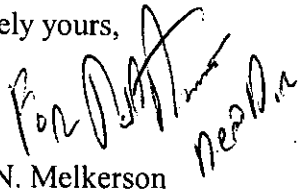
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100261

2. Indications for Use of the Device

510(k) Number (if known):

DEC 10 2010

Device Name: PriMatrix Ag Antimicrobial Dermal Repair Scaffold

Indications for Use:

PriMatrix Ag Antimicrobial 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Prescription Use _____ 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)

Neil Ogden for NKK, for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100261