



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

February 22, 2016

Integra LifeSciences Corp.
David D. Cox, Ph.D.
Vice President, Regulatory Affairs
Orthopedics and Tissue Technologies Division
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K153690
Trade/Device Name: PriMatrix Dermal Repair Scaffold
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 21, 2015
Received: December 23, 2015

Dear Dr. Cox:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Applicant Information:

Date Prepared: December 17, 2015
 Submitter: TEI BioSciences, Inc.

Address: 7 Elkins Street
 Boston, MA 02127

Establishment
 Registration No. 3004170064

Contact Person: David D. Cox, Ph.D.
 Vice President, Regulatory Affairs
 Integra LifeSciences (Owner of TEI Biosciences, Inc.)

Telephone Number: (609) 750-2880
 Fax Number: (609) 750-4277

II. Device Information:

Trade Name: PriMatrix™ Dermal Repair Scaffold
 Common Name: Animal-derived, dermal extracellular matrix wound care product

Classification Name: Dressing, Wound, Collagen
 Classification: Unclassified
 Product Code: KGN

Predicate Device: PriMatrix™ Dermal Repair Scaffold
 510(k) No. K131286; Product Code: KGN

Device 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

- 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
- Contraindications: PriMatrix should not be used for patients with a known history of hypersensitivity to collagen or bovine products.
- Comparison to Predicate Device(s): PriMatrix is exactly the same as the predicate in terms of materials, form, function and intended use. No changes in technology or packaging have been made to the predicate product. Only the labeling has been changed to add clarity.
- Test Data: No additional verification and validation test data were required as part of this submission. This "traditional" 510(k) was submitted to clarify and correct the labeling, without changing the Intended Use of PriMatrix.
- Summary: Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the PriMatrix product referenced in this submission is substantially equivalent to the currently marketed predicate device, and does not raise any new questions of safety or effectiveness.