

**510(K) SUMMARY**

**INTEGRA™ Meshed Bilayer Wound Matrix**

**DEC 04 2008**

**Submitter's name and address:**

Integra LifeSciences Corporation  
311 Enterprise Drive  
Plainsboro, NJ 08536 USA

**Contact person and telephone number:**

Diana Bordon  
Director, Regulatory Affairs  
Telephone: (609) 275-0500  
Fax: (609) 275-9445

**Date Summary was prepared:**

June 4, 2008

**Name of the device:**

Proprietary Name: INTEGRA™ Meshed Bilayer Wound Matrix  
Common Name: Wound Dressing  
Classification Name: Dressing, Wound, Drug  
Product Code: FRO

**Substantial Equivalence:**

INTEGRA™ Meshed Bilayer Wound Matrix is substantially equivalent in function and intended use to INTEGRA™ Bilayer Matrix Wound Dressing, which has been cleared to market under Premarket Notification 510(k) K021792.

**Device Description:**

INTEGRA™ Meshed Bilayer Wound Matrix is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan with a polysiloxane (silicone) layer. The meshed bilayer matrix allows drainage of wound exudate and provides a flexible adherent covering for the wound surface. The collagen- glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

**Intended Use:**

INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. May be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

**Testing and Test Results:**

INTEGRA™ Meshed Bilayer Wound Matrix and INTEGRA™ Bilayer Matrix Wound Dressing (K021792) are comprised of identical materials and are processed and sterilized by identical methods. Biocompatibility testing including Cytotoxicity, Dermal Sensitization, Irritation, Acute Systemic Toxicity, Pyrogenicity and Hemolysis were conducted for the INTEGRA Bilayer Matrix Wound Dressing product, in accordance with International Standard ISO 10993-1:1992, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests* and with Good Laboratory Practices. All test results were acceptable. These test results are applicable to the meshed product because, as noted above, the dressings are comprised of the same materials.

In addition to biocompatibility testing, the product is tested to meet the following performance characteristics. Pore size is determined using SEM and Image Analysis to provide a pre-determined functional pore size. In order to ensure that the native helical configuration of collagen is not significantly altered in the manufacturing process, the helical content in the collagen-glycosaminoglycan sponge is evaluated using Fourier Transform Infrared (FTIR) Spectrophotometry. Chondroitin-6-sulfate (C-6-S) is quantified using visible spectroscopy. The degree of cross-linking is determined using a colorimetric assay.

**Conclusion**

The results of the *in vitro* product characterization studies, performance testing and biocompatibility data demonstrate that INTEGRA Meshed Bilayer Wound Matrix is safe and substantially equivalent to its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Integra LifeSciences Corporation  
% Ms. Diana Bordon  
311 Enterprise Drive  
Plainsboro, New Jersey 08536

DEC 04 2008

Re: K081635

Trade/Device Name: INTEGRA™ Meshed Bilayer Wound Matrix

Regulatory Class: Unclassified

Product Code: FRO

Dated: October 30, 2008

Received: October 31, 2008

Dear Ms. Bordon:

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.

Page 2 – Ms. Diana Bordon

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K081635

Device Name: **INTEGRA™ Meshed Bilayer Wound Matrix**

**Indications For Use:** INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.


Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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 General, Restorative,  
and Neurological Devices

510(k) Number K081635