October 8, 2021

Integra LifeSciences Corporation
Nicole Kotter
Manager, Regulatory Affairs
1100 Campus Road
Princeton, New Jersey 08540

Re: K210128
Trade/Device Name: INTEGRA Wound Matrix (Macro-Channels)
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 15, 2021
Received: January 19, 2021

Dear Nicole Kotter:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210128

Device Name

INTEGRA® Wound Matrix (Macro-Channels)

Indications for Use *(Describe)*

INTEGRA® Wound Matrix (Macro-Channels) is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears) and draining wounds. The device is intended for one-time use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

INTEGRA® Wound Matrix (Macro-Channels)

I. SUBMITTER

Submitter's name and address:

Integra LifeSciences Corporation
1100 Campus Rd,
Princeton, NJ 08540 USA

Contact person and telephone number:

Saakshi Arora-Tice
Specialist, Regulatory Affairs
Telephone: 609.325.7374

Date Summary was prepared:

January 14, 2021

II. DEVICE

Name of the device:	INTEGRA® Wound Matrix (Macro-Channels)
Common Name:	Collagen Wound Dressing
Classification Name:	Not Classified
Regulatory Class:	Unclassified
Product Code:	KGN

III. PREDICATE DEVICE

INTEGRA® Wound Matrix (Macro-Channels) is substantially equivalent in technological characteristics and intended use to the predicate device detailed in the following table.

510(k) Number	Product Code	Trade Name	Manufacturer
K022127	KGN	INTEGRA® Wound Matrix (also known as Integra Matrix Wound Dressing)	Integra LifeSciences Corporation

The specific trade name AVAGEN Wound Dressing was cleared through 510(k) K022127 on September 10, 2002. Prior to official market release of AVAGEN Wound Dressing (K022127), Integra changed the product name from AVAGEN Wound Dressing to INTEGRA Matrix Wound Dressing in an effort to market a more uniform product family to consumers. The product name change from INTEGRA Matrix Wound Dressing to INTEGRA Wound Matrix was reflected in our INTEGRA Wound Matrix (Thin) 510(k) K113104 on February 9, 2012.

IV. DEVICE DESCRIPTION

INTEGRA® Wound Matrix (Macro-Channels) is a collagen-glycosaminoglycan wound dressing that maintains and supports a healing environment for wound management. INTEGRA® Wound Matrix (Macro-Channels) has macro-channels to facilitate drainage of wound exudate. INTEGRA® Wound Matrix (Macro-Channels) is supplied sterile and is intended for one-time use.

V. INDICATIONS FOR USE

INTEGRA® Wound Matrix (Macro-Channels) is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears) and draining wounds. The device is intended for one-time use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial Equivalence Comparison:

INTEGRA® Wound Matrix (Macro-Channels) is substantially equivalent in technological characteristics and intended use to the predicate device, which has been cleared under Premarket Notification 510(k) K022127. The modified device, INTEGRA® Wound Matrix (Macro-Channels), utilizes identical materials, manufacturing processes, packaging, and sterilization as the predicate device (K022127) except for an additional process step to introduce the presence of macro-channels (small holes) in the proposed device to facilitate fluid drainage through the device post-application. Further, the following technological characteristics, e.g., pore size, collagen-nativity, extent of collagen cross-linking, and glycosaminoglycan content, are identical between INTEGRA® Wound Matrix (Macro-Channels) and the predicate device INTEGRA® Wound Matrix (K022127). The table below provides a comparison between the predicate and subject device.

Product Name	INTEGRA® Wound Matrix (predicate device)	INTEGRA® Wound Matrix (Macro-Channels) (subject device)
510(k) Number	K022127	K210128
Product Code	KGN	KGN
Indications for Use	INTEGRA® Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser	INTEGRA® Wound Matrix (Macro-Channels) is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-

	surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.	Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears) and draining wounds. The device is intended for one-time use.
Design		
Physical Structure/Materials	Type I Bovine Collagen - glycosaminoglycan matrix	Type I Bovine Collagen - glycosaminoglycan matrix
Form	Sheet	Sheet
Perforations	No	Yes
Characteristics		
Dimensions	2"x2" (5 cm x 5cm) 4"x5" (10 cm x 12.5 cm) 4"x10" (10 cm x 25 cm) 8"x10" (20 cm x 25 cm)	2"x2" (5 cm x 5cm) 4"x5" (10 cm x 12.5 cm) 4"x10" (10 cm x 25 cm) 8"x10" (20 cm x 25 cm)
Resistance to collagenase Digestion	Optical Density Less than 0.800 absorbance unit	Optical Density Less than 0.800 absorbance unit
Endotoxin	Must be Less than 20 EU/device	Must be Less than 20 EU/device
Biocompatibility	Passes panel of ISO 10993 tests: Cytotoxicity, Dermal Irritation, Dermal Sensitization, Acute Systemic Toxicity, Hemolysis, Sub-chronic (sub-acute) Toxicity, Genotoxicity	Biocompatibility testing completed on INTEGRA® Wound Matrix was leveraged to support INTEGRA® Wound Matrix (Macro-Channels). Passes ISO 10993 tests for cytotoxicity.
Anatomical Location	Wounds	Wounds
Thickness	Approximately 0.8mm	Approximately 0.8mm
Sterility	e-beam irradiation, 10^{-6} SAL, single-use only	e-beam irradiation, 10^{-6} SAL, single-use only

VII. PERFORMANCE DATA:

INTEGRA® Wound Matrix (Macro-Channels) and INTEGRA® Wound Matrix (K022127) are comprised of identical materials and are processed and sterilized by similar methods.

Biocompatibility testing, including Cytotoxicity, Dermal Sensitization, Irritation, Acute Systemic Toxicity, Subchronic toxicity, Implantation, Genotoxicity, and Hemocompatibility tests, were conducted for the predicate device INTEGRA® Wound Matrix (K022127). All test results were acceptable. Due to the equivalent nature of the device composition, the biocompatibility testing completed on the INTEGRA® Wound Matrix (K022127) was leveraged to support the proposed device INTEGRA® Wound Matrix (Macro-Channels). In addition, the added manufacturing

process step was considered during the risk assessment for biocompatibility evaluations of the subject device, and the knowledge gaps were addressed through chemical analysis of manufacturing aids used during the process.

The proposed device is tested to ensure the following performance specifications are met: pore size, collagen nativity-FTIR test of denaturing, chondroitin-6-sulfate content, permeability, drapeability, degree of cross-linking, and bacterial endotoxin. In addition to bench performance tests, the *in vivo* safety and effectiveness of the INTEGRA® Wound Matrix (Macro-Channels) was assessed in a porcine wound healing model. The results of the study demonstrate that there are no significant differences in healing between the predicate and modified devices. Furthermore, the safe history of clinical use of similar collagen products, including the predicate device, manufactured, and marketed by Integra LifeSciences Corporation has been cited in this 510(k) Premarket Notification.

Conclusion:
The proposed INTEGRA® Wound Matrix (Macro-Channels) is substantially equivalent to the commercially marketed device, INTEGRA® Wound Matrix (K022127).

The modifications expressed in this 510(k) Premarket Notification do not change the intended use or fundamental scientific technology of the device and do not raise different questions of safety or effectiveness.