June 09, 2023

Novabone Products, LLC
% Linda Braddon
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K220498
Trade/Device Name: NovoGen Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 9, 2023
Received: May 10, 2023

Dear Linda Braddon:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.06.09 09:54:23 -04'00'

For Julie A. Morabito, Ph.D.
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)*
K220498

Device Name
NovoGen Wound Matrix

Indications for Use *(Describe)*
NovoGen 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 surgery, podiatric, wound dehiscence)
• Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears)
• Draining wounds

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
K220498
NovoGen Wound Matrix

Date Prepared	June 9, 2023
Sponsor	NovaBone Products, LLC 13510 NW US Highway 441 Alachua, FL 32615
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	NovoGen Wound Matrix
Common Name	Collagen Wound Matrix
Code – Classification	KGN Unclassified
Primary Predicate	K092096 Mesynthes Endoform Dermal Template
Reference Devices	K110368 NovaBone Putty - Bioactive Synthetic Bone Graft K112428 NovaBone Dental Morsels - Bioactive Synthetic Bone Graft K141207 NovaBone Bioactive Strip
Device Description	NovoGen Wound Matrix is a an absorbable, non-pyrogenic, sterile, single use device intended for use in local management of cutaneous wounds. It is manufactured from bovine type I collagen and 45S5 bioactive glass. When hydrated with wound exudate or sterile water, this product transforms into a soft conforming layer which is naturally incorporated into the wound over time.
Indications for Use Statement	NovoGen 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 surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) • Draining wounds

Comparison of Technological Characteristics

Trait	NovaBone Products, LLC NovaGen Wound Matrix (Subject Device)	Primary Predicate Mesynthes Ltd Endoform Dermal Template K092096
510(k) number	K220498	K092096
Regulation	Unclassified	Unclassified
Product Classification	KGN	KGN
Common Name	Collagen Wound Dressing	Collagen Wound Dressing
Indications for Use	NovoGen 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 surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) • Draining wounds	Endoform is supplied sterile and is intended for single use in the treatment of the following wounds: • 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, second-degree burns, and skin tears) • Draining wounds
Composition of Material	Bovine Collagen Bioactive Glass Citric Acid	Ovine collagen
Structural Reinforcement Material	Bioactive Glass (Same material as reference device K141207)	Not applicable
Primary Function	Wound Dressing	Wound Dressing
Absorbable	Yes	Not Stated, but websites say it will dissolve into the wound
Size(s)	Range of sizes from 26cm^2 to 130cm^2: • 2” x 2” (5.1cm x 5.1cm) • 2” x 3” (5.1cm x 7.6cm) • 3” x 3” (7.6cm x 7.6cm) • 4” x 5” (10.2cm x 12.7cm)	Range of sizes from 9cm^2 to 400cm^2

Trait	NovaBone Products, LLC NovaGen Wound Matrix (Subject Device)	Primary Predicate Mesynthes Ltd Endoform Dermal Template K092096
Fluid Absorbency	Yes	Not stated
Moist Environment	Maintains a moist wound environment	Not stated
Perforated	No	Perforated and Non-Perforated
Layers	One Layer	One or Two Layers
Customizable	Yes, trim to size	Yes, trim to size
Sterilization	Gamma, 10^{-6} SAL	Ethylene Oxide, 10^{-6} SAL
Packaging	Single peel packs	Not stated
Biocompatibility	Biocompatible	Biocompatible
Single Use	Yes	Yes
Reapplication	As needed	Every 5 to 7 days as needed
Non-Pyrogenic	Yes	Not specified

Technological Characteristics

NovoGen Wound Matrix is supplied terminally sterile in a sterile barrier packaging configuration. NovoGen Wound Matrix is a scaffold and is similar to other wound matrices with respect to its design. The subject device is composed of bovine collagen with Bioglass® 45S5 added as additional structural reinforcement.

There are no significant technological differences between the subject and predicate device. The subject device uses similar materials, is of a similar size and thickness, has similar design properties, and has the same intended use as the primary and additional predicates and reference devices. The presentation of the device in single vs dual peel pack packaging configuration does not create new risks for safety or effectiveness. The subject device uses the same packaging configuration as cleared in reference device K110368 NovaBone Putty - Bioactive Synthetic Bone Graft and uses the same sterilization process as cleared in reference device K112428 NovaBone Dental Morsels - Bioactive Synthetic Bone Graft.

Non-Clinical Performance Testing Summary

Performance testing for the NovaBone NovoGen Wound Matrix includes:

- Absorption Capacity
- Compression Recovery
- Degradation Potential via Collagenase
- Hydration Time
- Tensile Strength
- Viral Inactivation

A full thickness porcine wound healing study found equivalent wound healing performance for the NovaBone NovoGen Wound Matrix when compared to the primary predicate device and untreated control sites.

The NovaBone NovoGen Wound Matrix was found to be biocompatible for its intended use when tested in compliance with ISO 10993-1. Cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, subacute systemic toxicity, implantation, genotoxicity, and endotoxin endpoints were addressed via testing while chronic toxicity and carcinogenicity were addressed via a toxicological risk assessment.

A Human Repeat Insult Patch Test (HRIPT) was performed to determine the potential of the test material to elicit dermal irritation and/or induce sensitization following repeated patch applications in human subjects. The Induction Phase of the study is designed to assess the potential of the subject device to elicit an irritation reaction, whereas the Challenge Phase of the study is designed to assess the potential of the subject device to elicit a sensitization response.

Based on the test population who completed the study, NovoGen Wound Matrix did not demonstrate a potential for eliciting dermal irritation or inducing sensitization.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.