October 7, 2021

NeXtGen Biologics, Inc.
% Janice Hogan
Partner
Hogan Lovells LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K210024
Trade/Device Name: NeoMatriX Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 8, 2021
Received: September 8, 2021

Dear Janice Hogan:

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)*

K210024

Device Name

NeoMatriX® Wound Matrix

Indications for Use *(Describe)*

NeoMatriX® Wound Matrix is intended for 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, Moh's surgery, post-laser surgery, podiatric, and wound dehiscience),
- Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears),
- 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

NeXtGen™ Biologics, Inc.'s, NeoMatriX® Wound Matrix
K210024

Submitter: NeXtGen Biologics, Inc.
13709 Progress Blvd Box11
Alachua, FL 32615
Phone: 904-599-3264

Contact Person: Jonelle L. Toothman

Date Prepared: October 7, 2021

Name of Device: NeoMatriX® Wound Matrix

Common or Usual Name: Collagen Wound Dressing

Classification Name: Collagen Wound Dressing

Regulatory Class: Unclassified

Product Code: KGN

Predicate Devices: NeoMatriX® Wound Matrix (K181330)

Device Description

NeoMatriX Wound Matrix is a sterile, wound dressing fabricated from the dermal extracellular matrix of axolotl. This device is derived from an amphibian farm-raised hybrid axolotl source from a closed herd in a dedicated facility. NeoMatriX is provided as sheets of various sizes for placement on wound beds to help manage the wound environment. This device is terminally sterilized using gamma irradiation.

NeoMatriX wound matrix provides an adherent covering that protects the wound from the environment. The device is intended for one time use.

Intended Use / Indications for Use

NeoMatriX® Wound Matrix is intended for 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, and wound dehiscence),

- Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears),
- Draining wounds.

The device is intended for one-time use.

Substantial Equivalence

The subject device, NeoMatriX Wound Matrix, is a modification from the NeoMatriX Wound Matrix predicate previously cleared under K181331. There are no changes to the intended use or the release specifications. While there are minor changes to the manufacturing process, these changes are not expected to alter the device characteristics or performance, as the updated process steps are similar to the current steps. In-process evaluation uses similar methods as used by the predicate to ensure that the product meets the same acceptance criteria.

In addition, the company has repeated key nonclinical testing that was previously conducted in support of the predicate device to further confirm that the changes in the manufacturing process do not affect the characteristics or performance of the device.

Comparison between Subject Device and Predicate Device

	NeoMatriX® Wound Matrix **Subject Device (K210024)**	**NeoMatriX® Wound Matrix** **Predicate Device (K181330)**
Indications for Use	NeoMatriX® Wound Matrix is intended for 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, Moh's surgery, post-laser surgery, podiatric, and wound dehiscence), • Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears), • Draining wounds. The device is intended for one-time use.	NeoMatriX® Wound Matrix is intended for 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, Moh's surgery, post-laser surgery, podiatric, and wound dehiscence), • Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), • Draining wounds. The device is intended for one-time use.
Product Code	KGN - unclassified	KGN - unclassified
Technological Characteristics	Acellular – Extracellular matrix	Acellular – Extracellular matrix
Collagen source	Aquatic source - axolotl	Aquatic source - axolotl
Sterilization	Device is provided sterile for single-patient-use.	Device is provided sterile for single-patient-use.

Size	Supplied as sheets in various forms from 0.5cm^2 to 16.5cm^2	Supplied as sheets in various forms from 0.5cm^2 to 16.5cm^2
Size Customization	Variable sizes	Variable sizes
Processing	Device processed to remove cellular materials	Device processed to remove cellular materials
Packaging	Provided in double-pouched, peel-open packages	Provided in double-pouched, peel-open packages
Replacement Time	May be replaced on non-healed wound in 3-7 days as needed	May be replaced on non-healed wound in 3-7 days as needed

Performance Data

Biocompatibility testing per ISO 10993-1 standard, including cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, material mediated pyrogenicity, subacute and subchronic toxicity, and genotoxicity, as well as endotoxicity testing and viral inactivation testing consistent with FDA's guidance were conducted for the predicate NeoMatriX Wound Matrix (K181330). All test results were acceptable. The NeoMatriX predicate was also tested in a porcine model. Results showed no evidence of adverse effects, no inhibition in the re-epithelialization rate, and no necrosis in the superficial or deep wound beds. In addition, immunogenicity testing was conducted in human subjects, including a Human Repeated Insult Patch Test (HRIPT) in 68 healthy subjects and a Skin Prick Test (SPT) in 22 healthy human subjects. No reaction to NeoMatriX Wound Matrix was observed, indicating that NeoMatriX Wound Matrix does not raise immunogenicity concerns when used in humans.

Due to the equivalent nature of the device composition, the performance testing completed on the predicate NeoMatriX Wound Matrix (K181330) was leveraged to support the subject device. In addition, changes to the manufacturing process were considered during the risk assessment for the biocompatibility evaluations of the subject device and addressed through chemical analysis of the steps used during the manufacturing process. Key nonclinical testing that was previously conducted in support of the predicate device was repeated for the subject device. Results of collagen analysis of SDS-PAGE and HPLC-MS were equivalent compared to the results for the predicate. The histological and immunohistochemical evaluation of the subject NeoMatriX device processed from full-thickness axolotl skin is equivalent to the predicate NeoMatriX device. Immunochemical staining and biochemical assays to detect residual nuclear material showed similar performance after decellularization. Leachables and extractables testing and chemical characterization results further supported the lack of chemical contaminant from processing steps. Additionally, cytotoxicity and endotoxicity tests were repeated and the results were acceptable. Therefore, results from these tests confirm that the changes in the manufacturing process do not affect the characteristics or performance of the device.

Conclusions

NeoMatriX Wound Matrix and its predicate device have the same intended use and similar technological characteristics. The minor differences do not raise different questions of safety or effectiveness. Performance testing further demonstrates that the device is substantially equivalent to the predicate for its intended use.