October 11, 2018

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

Re: K181330
Trade/Device Name: NeoMatriX Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 11, 2018
Received: September 11, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181330

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, post 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.

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

K181330

General Company Information

Name:	NeXtGen Biologics, Inc.
Contact:	Jonelle L. Toothman
Address:	12085 Research Drive, Box 17 Alachua, FL 32615
Telephone:	352-215-9961
Email:	Jltoothman@nextgenbiologics.com

Date Prepared

October 3, 2018

General Device Information

Product Name: NeoMatriX® Wound Matrix

Classification: Collagen Wound Dressing (Product code: KGN)

Predicate Devices

Acell, Inc.	Cytal™ Wound Matrix (K152721) (Primary)
Acell, Inc.	MatriStem® Wound Matrix (K112409)
Cook Biotech, Inc.	Oasis™ Wound Matrix (K061711)

Reference Device

Kerecis, Ltd.	MariGen™ Wound Dressing (K132343)

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.

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, second-degree burns, and skin tears),
- Draining wounds.

The device is intended for one-time use.

Substantial Equivalence

NeoMatriX Wound Matrix has the same intended use as the predicate devices, which are all for management of wounds. The indications for use are also the same as the predicates. The technological characteristics of NeoMatriX Wound Matrix are substantially similar to the predicates, as all are provided in the form of sheets of decellularized collagen (extracellular matrix) that are placed on the surface of the patient's skin. Each of the collagen materials is obtained from animal tissue. All of the materials are processed to remove cellular material and for viral inactivation, and all are terminally sterilized. The NeoMatriX™ Wound Matrix and its predicates are applied directly to the wound, on the surface of the patient's skin for a specified time period (3 to 7 days). The main difference between the NeoMatriX Wound Matrix and the identified predicates is the animal source of collagen, which is the axolotl for NeoMatriX. However, this difference does not raise different questions of safety or effectiveness, as the key questions of biocompatibility, mechanical/physical properties, and safety for use in healing wounds are common to all devices. Furthermore, biocompatibility, performance testing, animal testing, and human clinical testing demonstrates that the device has appropriate properties for its intended use.

Performance Data

- **Biocompatibility Testing**

NeoMatriX Wound Matrix was subjected to the following biocompatibility testing per the ISO-10993-1 standard: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, subacute and subchronic toxicity, and genotoxicity. The results showed that NeoMatriX Wound Matrix meets biocompatibility requirements of the ISO standard. Endotoxin testing was conducted according to AAMI ST72. Viral inactivation testing was also performed.

- **Sterilization Validation**

NeoMatriX Wound Matrix is sterilized using gamma radiation to a sterility assurance level of 10^{-6}. In addition to application of the VD_{max} methodology, the gamma sterilization cycle is designed and validated per ISO 11137.

- **Bench Testing**

In vitro physio-chemical testing was conducted to demonstrate the chemical composition and physical characteristics of NeoMatriX Wound Matrix.

- **Animal Testing**

NeoMatriX Wound Matrix was subjected to porcine testing to demonstrate the performance of the device. Results showed that NeoMatriX did not inhibit wound healing when compared to the predicate device. No evidence of adverse effects was observed for either the NeoMatriX or predicate wound dressings. The two devices resulted in no inhibition or difference in the rate of re-epithelialization. Histopathology revealed no necrosis observed in the superficial or deep wound beds treated with the NeoMatriX or the predicate device. Epithelialization was comparable between the treatment groups.

- **Clinical Testing**

Immunogenicity testing was conducted in human subjects to further support the safety of the device. The clinical testing included 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 at any site in either clinical investigations, indicating that NeoMatriX Wound Matrix does not raise immunogenicity concerns when used in humans.

Conclusions

NeoMatriX Wound Matrix and its predicate devices have the same intended use and similar technological characteristics. The 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.