August 11, 2022

Bionova Medical Inc.
Alex Greene
Director, Clinical & Regulatory
3012 Centre Oak Way, Ste 102
Germantown, Tennessee 38138

Re: K210949
Trade/Device Name: Foundation Dermal Regeneration Scaffold (DRS) Solo
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 17, 2021
Received: May 18, 2021

Dear Alex Greene:

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,

Julie 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)*
K210949

Device Name
Foundation Dermal Regeneration Scaffold (DRS) Solo

Indications for Use *(Describe)*
Foundation DRS Solo is indicated for the management of wounds including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First degree burns
- Partial thickness burns (superficial second-degree burns)
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds (abrasions, lacerations, skin tears)
- Dehisced wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)

Foundation DRS Solo may be cut to size.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Applicant: Bionova Medical, Inc.
3012 Centre Oak Way, Suite 102
Germantown, TN 38138
Ph: (901) 748-2581
Fax: (901) 748-2583

Official Correspondent: Anike Freeman
Principal Consultant RQM+
Phone: (412) 899-7422
Email: afreeman@rqmplus.com

Date of Submission: 26 March 2021

Proprietary Name: Foundation Dermal Regeneration Scaffold (DRS) Solo
Common Name: Dressing, Wound, Drug
Regulatory Class: Unclassified

Product Codes: FRO
Predicate Devices:

- Primary predicate: K123961, Sentrex BioSponge MPD (Bionova Medical, Inc.)
- Reference Device: K081635, Integra Meshed Bilayer Wound Matrix (Integra LifeSciences Corp.)
- Reference Device: K021792, Integra Bilayer Wound Matrix (Integra LifeSciences Corp.)

Device Description:
Foundation DRS Solo is a highly conformable, advanced wound care device comprising a porous matrix of chitosan derived from shellfish and sodium chondroitin sulfate, a glycosaminoglycan. The chitosan- glycosaminoglycan biodegradable, porous matrix provides a scaffold for cellular invasion and capillary growth. The device is applied on the surface of the wound, and provides a moist wound environment. The dressing may be replaced or may remain in place, acting as a scaffold to promote cellular infiltration and capillary growth as the dressing degrades.

Intended Use:
Foundation DRS Solo is indicated for the management of wounds including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First degree burns
- Partial thickness burns (superficial second-degree burns)

- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds (abrasions, lacerations, skin tears)
- Dehisced wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)

Foundation DRS Solo may be cut to size.

Summary of Technological Characteristics and Substantial Equivalence Foundation DRS Solo is substantially equivalent in function and intended use to the predicate devices. It is a sterile, porous matrix made from chitosan, derived from shellfish, which is a non-toxic, biodegradable, biocompatible, natural-based biopolymer and sodium chondroitin sulfate, a glycosaminoglycan. The chitosan-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Summary of Nonclinical Testing
Biocompatibility testing was conducted for Foundation DRS Solo, in accordance with International Standard ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Guidance on selection of* tests and Good Laboratory Practices (GLP). The subject device was evaluated for:

- Cytotoxicity
- Intracutaneous Study in Rabbits
- Guinea Pig Max Sensitization
- Acute Systemic Toxicity in Mice
- Material-Mediated Rabbit Pyrogen Study
- Bacterial Reverse Mutation
- Genotoxicity Mouse Lymphoma Assay
- Systemic Toxicity Study with Full Thickness Skin Breach- 28 Days in Rats
- Implantation Test in Rabbits

Further, additional characterization testing was performed on the subject device including:

- Bacterial Endotoxins Testing (LAL) was performed in accordance with:
    - AAMI ST72 *Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing (2019)*
- Chemical Characterization (Extractables and Leachables) was performed in accordance with:
    - ISO 10993-18 *Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (2020)*
- Sterilization Validation was performed in accordance with:
    - ISO 14937 *Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (2009)*
    - ISO 10993-7 *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (2008)*

- Packaging Validation was performed in accordance with:
    - ANSI/AAMI/ISO 11607-1 *Packaging for Terminally Sterilized Medical Devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems ((2006(R2010)/A1:2014)*
    - ASTM D4169 *Standard Practice for Performance Testing of Shipping Containers and System (2016)*
    - ASTM F2096 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (2011)*
    - ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier* Materials (2015)

Performance testing was also performed including:

- Wound Healing Study in a Porcine Model
- Functionality Testing on Aged Devices
- Viral Inactivation was leveraged from the predicate device. The chitosan used in the subject device is identical and from the same supplier as the predicate device.

All tests found the device to meet study endpoints and meet acceptance criteria.

Determination of Substantial Equivalence

The claim of substantial equivalence of Foundation DRS to the predicate devices is based on the comparison of the intended use, device description, product technical/material characteristics, and performance characteristics. Foundation DRS Solo is substantially equivalent to the predicate device with regard to safety and effectiveness.