November 13, 2023

Bionova Medical, Inc.
% Lucie Dalet
Senior Consultant
Rqm+
2251 San Diego Ave
Suite B-257
San Diego, California 92110

Re: K231937
Trade/Device Name: Foundation Dermal Regeneration Scaffold (DRS) Solo
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 29, 2023
Received: June 30, 2023

Dear Lucie Dalet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231937

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
- 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.

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510(k) SUMMARY

DATE PREPARED
November 9, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Foundation Dermal Regeneration Scaffold (DRS) Solo
Common Name:	Dressing, Wound, Drug
Regulation Number:	Unclassified
Class:	Unclassified
Product Code:	FRO, KGN
Review Panel:	General & Plastic Surgery
Premarket Review:	Premarket Review by Infection Control and Plastic Surgery Devices (DH4TB)

PREDICATE DEVICE IDENTIFICATION
The Foundation DRS Solo is substantially equivalent to the following predicate and reference devices:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate*
K210949	Foundation Dermal Regeneration Scaffold (DRS) Solo / BioNova Medical, Inc.	Primary
K172140	NovoSorb BTM Wound Dressing / PolyNovo Biomaterials Pty Ltd	Secondary
K112888	Meso Wound Matrix / Kensey Nash Corporation	Secondary

510(k) Number	*Reference Device Name / Manufacturer*
K103787	Medeor™ Matrix / Kensey Nash Corporation
BK210661	RegenKit®-Wound Gel-2 / Regen Lab SA

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.

The Foundation DRS Solo is identical to the predicate cleared in K210949.

INDICATIONS FOR 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
- 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Bionova Medical Inc. believes that the Foundation DRS Solo is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same design and dimensions and uses identical materials as the devices cleared in K210949. The subject device has the same intended use and technological characteristics as the devices cleared in K210949. The only difference is an update to the labeling to include an option to moisten the device with autologous body fluids. This information is provided in the event the user chooses to hydrate with hydration fluids other than saline and does not affect the intended use, the technological characteristics, or the principle of operation of the device. The technological characteristics of the Foundation DRS Solo have undergone testing to ensure the device is as safe and effective as the primary predicate.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed on the subject device to demonstrate safety based on current industry standards:

- Hydration
- Dimensional stability
- Handing characteristics

In addition, since the subject and primary predicate devices have identical indications for use and technological characteristics, the following tests were leveraged from K210949:

- Biocompatibility:

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018. The subject device was evaluated for:

- Cytotoxicity per ISO 10993-5
- Intracutaneous Study in Rabbits per ISO 10993-10
- Guinea Pig Max Sensitization per ISO 10993-10
- Acute Systemic Toxicity in Mice per ISO 10993-11
- Material-Mediated Rabbit Pyrogen Study per ISO 10993-11 and USP <151>
- Bacterial Reverse Mutation per ISO 10993-3
- Genotoxicity Mouse Lymphoma Assay per ISO 10993-3
- Systemic Toxicity Study with Full Thickness Skin Breach- 28 Days in Rats per ISO 10993-11 and ISO 10993-6
- Chemical Characterization per ISO 10993-18

- Sterilization:

  Sterilization validation was performed in accordance with the following standards:
  - Sterilization validation per ISO 14937
  - Bacterial Endotoxins Testing (LAL) per AAMI ST72
  - Ethylene oxide sterilization residuals per ISO 10993-7

- Packaging:

  Packaging validation testing was performed according to the following standards:
  - ANSI/AAMI/ISO 11607-1
  - ASTM D4169
  - ASTM F2096
  - ASTM F88

- Performance Testing:
  - Wound Healing Study in a Porcine Model
  - Functionality Testing on Aged Devices
  - Viral Inactivation was leveraged from the device previously cleared in K123961. The chitosan used in the subject device is identical and from the same supplier as the device cleared in K123961.

The results of these tests indicate that the Foundation DRS Solo is substantially equivalent to the primary predicate device.

SUMMARY OF CLINICAL TESTING

Clinical testing was not required for the labeling update to include moistening of the device by autologous bodily fluids, in addition to saline.

CONCLUSION

The Foundation DRS Solo is the same device as the primary predicate device cleared in K210949, with the only change being a labeling change to include the addition of autologous body fluids as possible hydration fluids. Based on the testing performed, including hydration, dimensional stability as well as handling, it can be concluded that the subject device does not raise new questions of safety or effectiveness compared to the predicate devices. The similar intended use, technological characteristics, and performance characteristics of the subject device are considered substantially equivalent to the predicate devices.