August 21, 2024

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

Re: K240298
Trade/Device Name: Foundation Dermal Regeneration Scaffold Plus (DRS+) Duo
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 22, 2024
Received: July 22, 2024

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of 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)*
K240298

Device Name
Foundation Dermal Regeneration Scaffold Plus (DRS+) Duo

Indications for Use *(Describe)*
Foundation DRS+ Duo 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+ Duo 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
August 20, 2024

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DEVICE INFORMATION

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

PREDICATE DEVICE IDENTIFICATION
The Foundation DRS+ Duo is substantially equivalent to the following predicate device:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate*
K231937	Foundation Dermal Regeneration Scaffold (DRS) Solo / Bionova Medical, Inc.	Primary

DEVICE DESCRIPTION

Foundation DRS+ Duo is a conformable, advanced wound care device comprising a porous matrix of chitosan derived from shellfish, sodium chondroitin sulfate, a glycosaminoglycan, and hyaluronic acid. The chitosan- glycosaminoglycan- hyaluronic acid 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+ Duo has a semi-permeable polyurethane backing layer (offered with or without perforations) providing a flexible covering for the wound surface.

INDICATIONS FOR USE

Foundation DRS+ Duo 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+ Duo may be cut to size.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

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

The subject device has the same intended use, indications for use, design, principle of operation, and mechanism of action as the Foundation DRS Solo device (cleared in K231937). The only differences are the addition of hyaluronic acid to the matrix layer and the addition of a polyurethane backing layer offered in both perforated and non-perforated configurations.

The addition of the hyaluronic acid to the matrix layer and the addition of a backing layer do not change the technological characteristics of handling, cutting to size, wound coverage, or the way in which the user interfaces with the device. The addition of the hyaluronic acid to the matrix layer only slightly alters the material ratios and therefore does not have a substantial impact on

the product formulation. Based on the testing performed, including biocompatibility assessment, biocompatibility testing, and functional performance testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed device are assessed to be substantially equivalent to the primary predicate. A comparison table is provided at the end of this document.

SUMMARY OF NON-CLINICAL TESTING

Biocompatibility Testing:

Biocompatibility testing was conducted for Foundation DRS+ Duo, in accordance with International Standard ISO 10093-1:2018, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests* and Good Laboratory Practices (GLP). The subject device was evaluated for:

- Cytotoxicity per ISO 10993-5
- Intracutaneous reactivity per ISO 10993-23
- Sensitization per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Material-Mediated Pyrogenicity 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
- Implantation studies per ISO 10993-6
- Bacterial Endotoxins Test (BET) per ANSI/AAMI ST72:2019
- Biological Evaluation per ISO 10993-1

Performance Testing:

- Performance testing was assessed through additional endpoints within the Implantation (ISO 10993-6) model.
- Functionality Testing on Aged Devices with both saline and autologous body fluids:
  - Hydration
  - Dimensional Stability
  - Handling Characteristics
- Animal Testing:
  14, 28, 42, and 91-day implantation studies were conducted in a porcine wound healing model on full thickness dermal wounds. Wound healing characteristics and dynamics, biological response of the treatment sites, and residence time of the test articles in the treatment sites were evaluated.

In addition, since the subject and primary predicate devices have identical indications for use and substantially similar technological characteristics, the following tests were leveraged from K210949 and K231937:

- Sterilization:
  Sterilization validation was performed in accordance with the following standards:
  - Sterilization validation per ISO 14937
  - Ethylene oxide sterilization residuals per ISO 10993-7

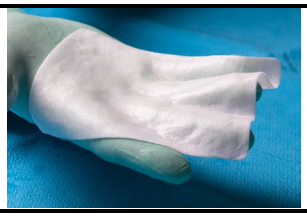
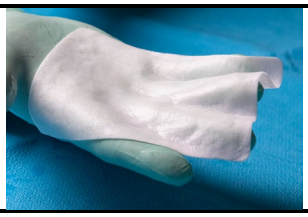
- Packaging:
  Packaging validation testing was performed according to the following standards:
  - ANSI/AAMI/ISO 11607-1
  - ASTM D4169
  - ASTM F2096
  - ASTM F88

- Viral Inactivation was leveraged from the device previously cleared in K231937. The chitosan used in the subject device is identical and from the same supplier as the device cleared in K231937.

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

SUMMARY OF CLINICAL TESTING
Clinical testing was not necessary to demonstrate substantial equivalence.

CONCLUSION
The determination of substantial equivalence of Foundation DRS+ Duo to the predicate device is based on the comparison of intended use, device description, product technical/material characteristics, and performance characteristics. Based on the testing performed, including biocompatibility testing, performance bench testing, and animal testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate device. The similar intended use, technological characteristics, and performance characteristics of the Foundation DRS+ Duo are considered substantially equivalent to the primary predicate device.

	Subject Device	***Primary Predicate Device***
	Bionova Medical Inc. Foundation Dermal Regeneration Scaffold Plus (DRS+) Duo	Bionova Medical Inc. Foundation Dermal Regeneration Scaffold (DRS) Solo K231937
Image		
Product Codes / Regulation Number	FRO, KGN Unclassified	Identical
Device Classification	FRO: Dressing, Wound, Drug KGN: Wound Dressing With Animal-Derived Material(s)	Identical
Materials	Chitosan, glycosaminoglycan, sodium hyaluronate (hyaluronic acid) Polyurethane backing layer	Chitosan, glycosaminoglycan
Indications for Use	Foundation DRS+ Duo 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.	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.
Hydration	Saline Autologous body fluids	Identical
Supplied	Sterile	Identical
Sterilization Method	Ethylene Oxide	Identical