January 6, 2025

FesariusTherapeutics Inc.
% Diana Bordon
Sr. Director, Regulatory Affairs, Regenity Biosciences
Regenity Biosciences
115 W. Century Rd. Suite 380
Paramus, New Jersey 07652

Re: K241904
Trade/Device Name: DermiSphere™ *h*DRT
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 6, 2024
Received: December 6, 2024

Dear Diana Bordon:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241904

Device Name
DermiSphere™ hDRT hydrogel Dermal Regeneration Template

Indications for Use *(Describe)*
DermiSphere™ hDRT hydrogel Dermal Regeneration Template is a wound dressing indicated for the 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, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds. This 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.

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

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Contact Details

Applicant Name:	FesariusTherapeutics Inc.
Applicant Address:	619 West 54th Street New York NY 10019 United States
Applicant Contact Telephone:	(516) 301-7047
Applicant Contact:	Dr. Yulia Sapir-Lekhovitser Chief Scientific Officer

Date Prepared:	January 04, 2025

Device Name

Device Trade Name:	DermiSphere™ *h*DRT K241904
Device Common Name(s):	Dermal Regeneration Template
Device Classification Name:	Wound dressing with animal derived materials KGN Unclassified

Predicate Device

K022127

Device Trade Name:	Avagen Matrix Wound Dressing
Device Classification:	KGN Unclassified

Device Description Summary

DermiSphere™ *h*DRT *hydrogel* Dermal Regeneration Template is an advanced wound dressing comprised of crosslinked bovine collagen microspheres embedded in bovine collagen hydrogel matrix. This composite biodegradable wound dressing provides a scaffold for native tissue cellular invasion and capillary growth.

Intended Use

DermiSphere™ *h*DRT *hydrogel* Dermal Regeneration Template is a wound dressing indicated for the 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, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds. This device is intended for one-time use.

Technological Comparison

The subject device, DermiSphere™ *h*DRT *hydrogel* Dermal Template, has the same intended use, indications, principals of operation, basic design and performance as the predicate device, Avagen Wound Dressing (K022127). The subject and predicate devices have very similar technological characteristics. The predicate device is a porous matrix comprised of crosslinked Type I collagen derived from bovine Achilles tendon, with the fractional addition of glycosaminoglycan (GAG). In contrast, the subject device is a hydrogel matrix comprised of Type I collagen derived from bovine dermis only and a crosslinked subcomponent (collagen spheres). Both resulting devices are comprised of a collagenous matrix that provides a scaffold for cellular invasion and capillary growth. Both devices consist primarily of Type I bovine collagen. Together, the material differences between the subject device and predicate are not significant and support substantially equivalent modes of action for their shared intended use.

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. A comparison of the subject device to the predicate device is provided in the following table.

Feature	Subject Device - K241904	Predicate Device - K022127
Indications for Use Statement	DermiSphere™ *h*DRT *hydrogel* Dermal Regeneration Template is a wound dressing indicated for the 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, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.	Avagen Wound Dressing is indicated for the 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, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.
Device Description	DermiSphere™ *h*DRT *hydrogel* Dermal Regeneration Template is an advanced wound dressing comprised of crosslinked bovine collagen microspheres embedded in bovine collagen hydrogel matrix. This composite biodegradable wound dressing provides a scaffold for native tissue cellular invasion and capillary growth.	Avagen Wound Dressing is an advanced wound dressing composed of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan. The biodegradable matrix provides a scaffold for cellular invasion and capillary growth.
Material Composition	Type I bovine collagen	Type I bovine collagen Glycosaminoglycan (GAG)
Animal Tissue Source	Bovine Dermis	Bovine Tendon (collagen) Shark Cartilage (GAG)
Crosslinking	Material component (microspheres) crosslinked	Full product crosslinked
Collagen Stability	Adequate stability to support cellular integration and vascularization	Adequate stability to support cellular integration and vascularization
Drapability	7.88 ± 0.21 mm	8.97 ± 1.62 mm*
Product Sizes	4 cm x 5 cm 10 cm x 12 cm	10 cm x 12.5 cm 10 cm x 25 cm 20 cm x 25 cm
Sterile	Sterile, SAL 10^{-6} using irradiation	Sterile, SAL 10^{-6} using irradiation

* The values are derived by Fesarius testing

Non-Clinical and/or Clinical Tests Summary & Conclusions

In vivo and in vitro testing of the subject device was conducted to demonstrate substantial equivalence of the subject device to its predicate device. The following safety and performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

A series of biocompatibility testing was performed in accordance with the testing matrix of ISO 10993-1 and an exhaustive extraction chemical characterization was conducted in accordance with ISO 10993-18 to assess the safety of DermiSphere™ *h*DRT *hydrogel* Dermal Regeneration Template.

Bench Testing

Product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate. Testing included, but was not limited to, dimensions, drapability, and pyrogenicity.

Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to its predicate device. The safety and effectiveness of the subject device has been demonstrated through bench testing, biocompatibility and substantial equivalence comparison to the predicate devices.