May 14, 2025

Helios Biomedical Inc.
℅ Roshana Ahmed
President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K250420
Trade/Device Name: Helios Dura Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: February 13, 2025
Received: February 13, 2025

Dear Roshana Ahmed:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.05.14 11:28:12 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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.

Submission Number *(if known)*

K250420

Device Name

Helios Dura Regeneration Matrix

Indications for Use *(Describe)*

Helios Dura Regeneration Matrix is indicated as a dura substitute for the repair of the dura mater.

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

I. Submitter

Helios Biomedical Inc.
11 Dellbrook Road
Weston MA 02493
Phone: (617) 818-4008

Contact Person: Yiannis Monovoukas, President & CEO

Date Prepared: May 14, 2025

II. Device

Device Proprietary Name:	Helios Dura Regeneration Matrix
Common or Usual Name:	Dura Substitute
Classification Name:	Dura Substitute
Regulation Number:	21 CFR §882.5910
Product Code:	GXQ
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Durepair® Dura Regeneration Matrix, K161370, Medtronic Neurosurgery

The following devices are cited as reference devices within the submission:

- CardiaMend™ Pericardial and Epicardial Reconstruction Matrix, K210331, Helios Cardio Inc.
- SurgiMend™ Collagen Matrix for Soft Tissue Reconstruction, K161370, Integra Lifesciences/TEI Biosciences.

IV. Device Description

Helios Dura Regeneration Matrix is a collagen implant for the repair of defects in the dura mater. The single-use device is supplied sterile in sheet form in a variety of sizes ranging from 6.5 - 250 cm^2 (~1 - 40-in^2) to be trimmed and sutured or onlayed by the surgeon to meet the individual patient's needs.

V. Indications for Use

Helios Dura Regeneration Matrix is indicated as a dura substitute for the repair of the dura mater.

VI. Technological Characteristics

Helios Dura Regeneration Matrix is substantially equivalent to the predicate device, Durepair® Dura Regeneration Matrix (K161370), with respect to the intended use and technological characteristics. A comparison of the two devices is provided in the table below.

	Helios Dura Regeneration Matrix	**Durepair® Dura Regeneration Matrix (K161370)**	**Analysis**
Indications for Use	Indicated as a dura substitute for the repair of the dura mater.	Indicated as a dura substitute for the repair of the dura mater.	Identical
Reusable or single use	Single-Use	Single-Use	Identical
Material	Collagen, extracellular matrix	Collagen, extracellular matrix	Identical
Animal Tissue Source	Fetal bovine dermis	Fetal bovine dermis	Identical
Fundamental Technology	Acellular dermal matrix collagen implant for the repair of defects in the dura mater	Acellular dermal matrix collagen implant for the repair of defects in the dura mater	Identical
Form	Square or rectangle	Square or rectangle	Identical
Design	Solid sheet	Solid sheet	Identical
Size	6.5 - 250 cm^2	1 - 40 in^2 (~6.5 - 250 cm^2)	Substantially Equivalent

	Helios Dura Regeneration Matrix	Durepair® Dura Regeneration Matrix (K161370)	Analysis
Number of Layers	Single-ply	Single-ply	Identical
Sterilization	Ethylene oxide; SAL 10^{-6}	Ethylene oxide; SAL 10^{-6}	Identical
Storage	Store dry, at room temperature (15 ℃ - 30 ℃)	Store dry, at room temperature (15 ℃ - 30 ℃)	Identical
Shelf Life	Three (3) years from the date of lyophilization	Three (3) years from the date of lyophilization	Identical

Helios Dura Regeneration Matrix is identical to the predicate device in terms of fundamental technology, indications for use, materials, form, design, appearance, function, lack of chemical crosslinking, lyophilization, sterilization, storage, packaging, biocompatibility, and shelf life.

VII. Performance Data

Helios Dura Regeneration Matrix is identical to the reference devices CardiaMend™ Pericardial and Epicardial Reconstruction Matrix (K210331) and/or SurgiMend™ Collagen Matrix for Soft Tissue Reconstruction (K071807) with respect to fundamental technology, materials, manufacturing process, , sterilization, storage, biocompatibility, and shelf life; therefore, existing data from CardiaMend™ Pericardial and Epicardial Reconstruction Matrix and/or SurgiMend™ Collagen Matrix for Soft Tissue Reconstruction was leveraged in support of the substantial equivalence determination:

- Device Characterization Testing
  - Dimensional verification
  - Color and appearance
  - Suture Retention Strength
  - Acellularity (Histology)
  - Collagen Denaturation
- Design Validations
  - Viral Inactivation
  - Sterilization
- Biocompatibility
- Shelf-life

- Packaging testing

VIII. Conclusion

Helios Dura Regeneration Matrix is substantially equivalent to the specified predicate device based on comparisons of device functionality, material, technological characteristics, and indications for use.