December 15, 2025

Spineology Inc.
Megan Polos
Senior Regulatory Affairs Specialist
7800 3rd Street North
Suite 600
Saint Paul, Minnesota 55128

Re: K251302
Trade/Device Name: OptiMesh Multiplanar Expandable Interbody Fusion System
Regulation Number: 21 CFR 888.3085
Regulation Name: Intervertebral Body Graft Containment Device
Regulatory Class: Class II
Product Code: OQB
Dated: November 26, 2025
Received: November 26, 2025

Dear Megan Polos:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*

K251302

Device Name

OptiMesh Multiplanar Expandable Interbody Fusion System

Indications for Use *(Describe)*

The OptiMesh Multiplanar Expandable Interbody Fusion System is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. The OptiMesh device, along with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion, is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

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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Spineology®

510(k) Summary

Date Prepared:	December 11, 2025
Submitter:	Spineology Inc. 7800 3rd Street North Suite 600 Saint Paul, MN 55128 Establishment Registration Number: 2135156
Contact Person:	Megan Polos Senior Regulatory Affairs Specialist Phone: 651.256.8500 Email: mpolos@spineology.com

Device Name and Classification

Trade Name:	OptiMesh Multiplanar Expandable Interbody Fusion System
Classification Name:	Intervertebral Body Graft Containment Device
Product Codes:	OQB
Regulatory Class:	Class II (Special Controls)
Regulation Number:	21 CFR 888.3085
Panel:	Orthopedic

Predicate Devices

Primary:	K230927	OptiMesh Multiplanar Expandable Interbody Fusion System
Reference:	K242509	HA*nano* InterFuse® Modular Interbody

1. Purpose

The purpose of this premarket notification is to obtain FDA clearance for a line extension of Implants to the OptiMesh Multiplanar Expandable Interbody Fusion System. The subject Implants incorporate a hydroxyapatite (HA^{nano} Surface®) treatment to the Implant portfolio. The HA^{nano} Surface® treatment presents a nano-scale topography on the entirety of the mesh component surface.

2. Device Description

The OptiMesh Multiplanar Expandable Interbody Fusion System is an intervertebral body graft containment device that is a non-rigid, implanted spinal device designed to contain FDA cleared bone void filler within its internal cavity. The device is inserted into the intervertebral body space of the spine and is intended as an adjunct to intervertebral body fusion.

The OptiMesh implants are available with and without HA^{nano} Surface®, a 20 – 40 nanometer thin hydroxyapatite (HA) surfaces treatment.

3. Indications for Use

The OptiMesh Multiplanar Expandable Interbody Fusion System is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. The OptiMesh device, along with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion, is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

4. Technological Characteristics

The subject OptiMesh HA^{nano} device is identical in technological characteristics to the predicate device but incorporates a nano-scale HA surface treatment which is identical in material to that provided on the reference device. The differences in technological characteristics do not raise difference questions of safety and effectiveness.

5. Non-Clinical Performance Testing

The technological design features of the subject device are identical to the predicate device in intended use, indications for use, geometric design, design function, and technology, apart from the proposed addition of a hydroxyapatite surface treatment. Non-clinical testing was conducted to support the subject HA surface treated implants confirming function and performance and to demonstrate substantial equivalence.

- Benchtop functional and mechanical characterization testing and comparison confirmed that the subject HA surface treated implants function as intended in comparison to the predicate device.
- Benchtop performance adhesion testing confirmed mechanical function and material strength characteristics of the subject HA surface treated implants in comparison to the predicate device, with support from the reference device.
- Benchtop performance ASTM testing and comparison confirmed that the subject HA surface treated implants perform as intended in comparison to the predicate device.

6. Clinical Performance Testing

Clinical performance testing was not necessary to support the subject OptiMesh HA^{nano} implants.

7. Conclusion

The subject OptiMesh HA^{nano} implants have been shown to be substantially equivalent to the legally marketed predicate device.