



October 18, 2023

Spineology Inc.
Andrew Adams
Group Director of Regulatory & Quality Affairs
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K231781

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: September 22, 2023
Received: September 25, 2023

Dear Andrew Adams:

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,

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

Indications for Use

510(k) Number (if known)

K231781

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 with compatible allograft and autograft 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.

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510(k) Summary

Date Prepared: October 13, 2023

Submitter: Spineology Inc.
7800 3rd Street North
Suite 600
Saint Paul, MN 55128
Establishment Registration Number: 2135156

Contact Person: Andrew Adams
Group Director of Regulatory & Quality Affairs
Phone: 651.256.8500
Fax: 651.256.8505
Email: aadams@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
Regulation Number: 21 CFR 888.3085
Panel: Orthopedic

Predicate Device

Primary:	DEN200010	Spineology Interbody Fusion System
Reference:	K192047	Rampart™ One Lumbar Interbody Fusion System

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 add lordotic configurations to the Implant portfolio. This submission also includes Class II surgical instruments unique to the implantation of the device.

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 bone graft 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 Lordotic device incorporates an asymmetrical dual chamber mesh with a larger chamber in the anterior portion of the disc space than in the posterior. Due to the asymmetry of the two mesh chambers when filled, the implant is designed to result in a lordotic shape.

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 with compatible allograft and autograft is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

4. Technological Characteristics

When compared to the predicate device, the subject lordotic implants have the same intended use and the same, or equivalent, technological characteristics, including:

- | | |
|-------------------------------------|---------------------------------------|
| • Indications for Use | • Device Design |
| • Primary Design Features | • Principle of Operation |
| • Materials of Construction | • Risk Profile |
| • Function / Performance | • Use with Compatible Fill Material |
| • Fundamental Scientific Technology | • Use with Posterior Fixation Systems |

5. Non-Clinical Testing

Non-clinical testing was conducted to support the subject lordotic implants confirming function and performance and to demonstrate substantial equivalence.

- A review of the design changes was performed and confirmed that these modifications do not alter the intended use or present new technological characteristics.
- The design changes do not alter the primary control mechanism or operating principle.
- Benchtop performance ASTM testing and comparison confirmed that the subject lordotic implants perform as intended in comparison to the predicate device and ISO 23089-2 mechanical performance data.
- A risk assessment was performed and confirmed that the modifications introduced do not alter the risk profile for the device or present new issues of safety or effectiveness when compared to the predicate device.

6. Conclusion

Based on the intended use, technological characteristics, and comparison to the predicate device, the subject lordotic implants have been shown to be substantially equivalent to the legally marketed predicate device.