November 1, 2023

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

Re: K230927
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, MBP
Dated: March 31, 2023
Received: April 3, 2023

Dear Mr. 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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2023.11.01 14:56:03 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230927

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, or 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K230927

Device Name

AFT Allograft Filler Tube

Indications for Use *(Describe)*

AFT is intended for use as a bone void filler in the extremities, spine, intervertebral disc space, and pelvis for voids or gaps that are not intrinsic to the stability of the bony structure. AFT is indicated for use in the treatment of osseous defects caused by surgery or traumatic injury. When used in intervertebral body fusion procedures, AFT must be used on its own with an intervertebral body graft containment device cleared by FDA for use with a bone void filler.

AFT is intended for single patient use only.

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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Spineology

510(k) Summary

Date Prepared: October 25, 2023

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

Contact Person:
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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

Trade Name:	AFT Allograft Filler Tube
Classification Name:	Resorbable Calcium Salt Bone Void Filler Device
Product Codes:	MBP
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3045
Panel:	Orthopedic

Predicate Device

Primary:	K203714	Thoracolumbar Interbody Systems and Attrax Putty
Reference:	DEN200010	Spineology Interbody Fusion System
Reference:	K060161	AFT Allograft Filler Tube

1. Purpose

The purpose of this premarket notification is to obtain FDA clearance for the addition of AFT Allograft Filler Tube as a compatible allograft for use with the OptiMesh Multiplanar Interbody Fusion System (formerly branded as Spineology Interbody Fusion System).

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 that is 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.

AFT Allograft Filler Tube is composed of human demineralized bone matrix, human non-demineralized bone, and sodium hyaluronate. All components of AFT are resorbable. AFT is aseptically processed and provided pre-loaded into a disposable delivery tube.

3. Indications for Use

OptiMesh Multiplanar Expandable Interbody Fusion System

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, or 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.

AFT Allograft Filler Tube

AFT is intended for use as a bone void filler in the extremities, spine, intervertebral disc space, and pelvis for voids or gaps that are not intrinsic to the stability of the bony structure. AFT is indicated for use in the treatment of osseous defects caused by surgery or traumatic injury. When used in intervertebral body fusion procedures, AFT must be used on its own with an intervertebral body graft containment device cleared by FDA for use with a bone void filler.

AFT is intended for single patient use only.

4. Technological Characteristics

When compared to the predicate device, the OptiMesh Multiplanar Expandable Interbody Fusion System with AFT has the same intended use and the same or similar technological characteristics, including:

- Indications for Use
- Function / Performance
- Control Mechanism
- Energy Type
- Principle of Operation
- Use with Compatible Fill Material
- Use with Supplemental Fixation Systems

Different technological characteristics exist, including:

- Materials of Construction
- Structure of Construction
- Mechanism of Mechanical Support

The subject OptiMesh interbody device and AFT bone void filler device are identical in technological characteristics to the reference devices. The reference devices support the comparison of the subject device to the primary predicate device, particularly that the differences in technological characteristics do not raise different questions of safety and effectiveness.

5. Non-Clinical Testing

Non-clinical testing was conducted to support AFT as a compatible allograft for use with the OptiMesh device confirming function and performance.

- Benchtop mechanical ASTM testing and comparison confirmed that the OptiMesh device with AFT performs as intended in comparison to the reference device and ISO 23089-2 mechanical performance data.
- A critical comparison between AFT bone void filler and the reference bone graft and its impact on bone biology was conducted and assessed.
- Biocompatibility, pyrogenicity / endotoxin monitoring, sterilization, packaging, and shelf-life were compared and assessed.
- A risk assessment was performed and confirmed that the OptiMesh device with AFT does not alter the risk profile for the device or present new issues of safety or effectiveness when compared to the predicate device.

6. Clinical Performance Data

Clinical data has been utilized to demonstrate the performance and safety of the addition of AFT as a compatible allograft for use with the OptiMesh Multiplanar Interbody Fusion System. The clinical data includes evaluation through a critical engineering and clinical comparison to a bone graft that was used in a prospective, multi-center, non-randomized, FDA and IRB approved performance goal clinical investigation. This evaluation supports the performance of the subject device for its intended use.

7. Conclusion

Based on the intended use, technological characteristics, comparison to the predicate device, and support from the reference devices, the subject addition of AFT Allograft Filler Tube as a compatible allograft for use with the OptiMesh Multiplanar Expandable Interbody Fusion System has been shown to be substantially equivalent to the legally marketed predicate device.