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

September 18, 2020

Re: DEN200010
Trade/Device Name: Spineology Interbody Fusion System
Regulation Number: 21 CFR 888.3085
Regulation Name: Intervertebral body graft containment device
Regulatory Class: Class II
Product Code: OQB
Dated: February 14, 2020
Received: February 19, 2020

Dear Mr. Adams:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Spineology Interbody Fusion System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Spineology Interbody Fusion System (SIFS) 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 1 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. SIFS with compatible allograft and autograft is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Spineology Interbody Fusion System, and substantially equivalent devices of this generic type, into Class II under the generic name intervertebral body graft containment device.

FDA identifies this generic type of device as:

> **Intervertebral body graft containment device**. An intervertebral body graft containment device 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two

options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 19, 2020, FDA received your De Novo requesting classification of the Spineology Interbody Fusion System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Spineology Interbody Fusion System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Spineology Interbody Fusion System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Design characteristics Biocompatibility evaluation Sterilization/reprocessing validation Labeling
Infection	Sterilization/reprocessing validation Labeling
Loosening/migration due to device failure or failure at the bone/implant interface	Design characteristics Clinical performance testing Non-clinical performance testing Biocompatibility evaluation Labeling
Tissue Injury	Labeling
Pseudarthrosis due to device failure or failure at the bone-implant interface	Clinical performance testing Non-clinical performance testing Biocompatibility evaluation Labeling
Adverse clinical sequelae	Clinical performance testing Labeling
Use error/Improper device use	Labeling

In combination with the general controls of the FD&C Act, the intervertebral body graft containment device is subject to the following special controls:

(1) Clinical performance testing must include an assessment of any adverse events observed during clinical use, as well as intervertebral body fusion, and compare this to a clinically acceptable fusion rate.
(2) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant, as well as the ability of the device to be inserted, deployed, and filled with bone graft consistently.
(3) Device must be demonstrated to be biocompatible.
(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components, and device-specific instruments.
(5) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
(6) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:
    (i) A clear description of the technological features of the device including identification of device materials, compatible components in the fusion construct, and the principles of device operation;
    (ii) Intended use and indications for use, including levels of fixation;
    (iii) Identification of magnetic resonance (MR) compatibility status;
    (iv) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
    (v) Detailed instructions of each surgical step, including device removal.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the intervertebral body graft containment device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for

combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Aakash Jain at 240-402-7531.

Sincerely,

Mark N. Melkerson -S

for CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health