February 19, 2021

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

Re: K210155
Trade/Device Name: Duo™ Expandable Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 20, 2021
Received: January 21, 2021

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210155

Device Name
Duo™ Expandable Interbody Fusion System

Indications for Use *(Describe)*

The Duo™ Expandable Interbody Fusion System is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to L5 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Duo device is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA 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."

Duo™ Expandable Interbody Fusion System

Spineology

510(k) Summary

Date Prepared: February 17, 2021

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:	Duo™ Expandable Interbody Fusion System
Classification Name:	Intervertebral Body Fusion Device
Product Code:	MAX
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3080
Panel:	Orthopedic

Predicate Devices

Primary:	K190055	Duo™ Lumbar Interbody Fusion Device
Additional:	K183705	IdentiTi™ Porous Ti Interbody System

1. Purpose

The purpose of this premarket notification is to obtain FDA clearance for a line extension of Implants and Implant Trials to the Duo Expandable Interbody Fusion System. The subject Duo Ti Implants incorporate spacer blocks that are wider and constructed of OsteoSync™ porous titanium.

2. Device Description

The Duo Expandable Interbody Fusion System is an intervertebral implant designed to provide mechanical support of the intradiscal space as an adjunct to fusion. The device is made of PEEK-OPTIMA® LT-1, titanium alloy, polyethylene terephthalate (PET), and tantalum or OsteoSync™ titanium, titanium alloy, and PET. The Duo implant is available in varying lengths, widths, heights, lordotic angles and is provided sterile. The implant is designed with a porous central cavity for graft containment, a rounded nose to aid in implant insertion, and rigid teeth to resist migration.

3. Indications for Use

The Duo™ Expandable Interbody Fusion System is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to L5 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Duo device is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

4. Technological Characteristics

When compared to the predicate devices, the subject Duo Ti Implants and Implant Trials have the same intended use and the same, or equivalent, technological characteristics, including:

- Indications for Use
- Primary Design Features
- Materials of Construction
- Function / Performance
- Fundamental Scientific Technology
- Device Design
- Principle of Operation
- Risk Profile
- Use with Supplemental Fixation Systems

5. Non-Clinical Testing

Non-clinical testing was conducted to support the subject Duo Ti Implants and Implant Trials 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 mechanical construct and performance ASTM testing and comparison confirmed that the subject implants perform as intended in comparison to the predicate devices.
- 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 devices.

6. Conclusion

Based on the intended use, technological characteristics, and comparison to the predicate devices, the Duo Ti Expandable Interbody Fusion System has been shown to be substantially equivalent to the legally marketed predicate devices.