Spineology Inc.
Karen Roche
VP, Operations & Technology
7800 Third Street N., Suite 600
St. Paul, Minnesota 55128

August 14, 2018

Re: K181792
Trade/Device Name: Duo™ Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 25, 2018
Received: July 26, 2018

Dear Ms. Roche:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K181792

Device Name
Duo™ Lumbar Interbody Fusion Device

Indications for Use *(Describe)*

The Duo™ Lumbar Interbody Fusion Device 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.

510(k) Summary

Date Prepared: July 3, 2018

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

Contact Person: Karen Roche
Vice President, Operations and Technology
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Email: kroche@spineology.com

Device Name and Classification

Trade Names:	Duo™ Lumbar Interbody Fusion Device
Common Name:	Intervertebral body fusion device
Product Code:	MAX
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3080
Panel:	Orthopedic
Predicate Device:	K171660 Duo™ Lumbar Interbody Fusion Device (Spineology Inc.)

A. Device Description

The Duo™ Lumbar Interbody Fusion Device 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. The Duo implant is available in varying lengths and heights with two lordotic configurations, and is provided sterile. The device is designed with a porous central cavity for graft containment, rounded nose to aid implant insertion, and ridged teeth to resist migration.

B. Indications for Use

The Duo™ Lumbar Interbody Fusion Device 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.

C. Comparison to Predicate

When compared to the predicate device, the modified Duo System has the same or equivalent:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Materials of Construction
- Risk Profile

D. Non-Clinical Testing

Duo Surgical Instrumentation: Where applicable, verification testing was performed to support modifications to the Duo surgical instrumentation.

- A review of the design changes to the Duo surgical instrumentation was performed and confirmed that these modifications do not present new technological characteristics or alter the intended use of these devices.
- For surgical instruments which are intended to interface with the Duo implant, the implant/instrument interface remains unchanged.
- The design changes included modifications to maintain or improve surgical instrument ergonomics and usability but do not alter the primary control mechanism or operating principle of the instrument.
- A risk assessment was performed and confirmed that the modifications to the Duo surgical instruments do not alter the risk profile for the device or present new issues of safety or effectiveness.

E. Conclusion

Based on individual and collective review of the modification to the Duo System, Spineology has demonstrated that the modified Duo System is substantially equivalent to the predicate device.