



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

October 24, 2018

Re: K182322

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: August 24, 2018
Received: August 27, 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,

Katherine D. Kavlock -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182322

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.

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**510(k) Summary**

Date Prepared: October 17, 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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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 Devices:	
Primary:	K181792 Duo Lumbar Interbody Fusion Device (Spineology Inc.)
Additional:	K133614 Aleutian IBF System (K2M, 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 three lordotic configurations and is provided sterile. The device is designed with a porous central cavity for graft containment, a 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 similar:

- Intended Use
- Indications for Use
- Principle of Operation
- Materials of Construction

- Fundamental Scientific Technology
- Risk Profile
- Size Offering

D. Non-Clinical Testing

Duo implant: The primary predicate device was previously tested in static and dynamic axial compression and compression-shear, subsidence, and expulsion. Engineering analysis and verification testing (expulsion testing) supported this implant line extension.

E. Conclusion

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