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August 28, 2020

Spinal Stability, LLC
% J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Inc
4313 W. 3800 S.
West Haven, Utah 84401

Re: K200958
Trade/Device Name: MODULIF-A Anterior Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 28, 2020
Received: July 31, 2020

Dear Mr. Webb:

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.
Acting 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)*
K200958

Device Name
MODULIF-A Anterior Lumbar Interbody Fusion System

Indications for Use *(Describe)*

MODULIF-A is an interbody fusion device intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal procedure at the involved level(s).

The device system is designed for use with supplemental fixation and with autogenous or allograft bone graft comprised of cancellous and / or corticocancellous bone graft to facilitate fusion. Patients should have six months of non-operative treatment prior to treatment with an interbody fusion cage. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device.

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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*5*10(k) Summary: MODULIF-A Anterior Lumbar Interbody Fusion System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	July 13, 2020
Submitted By	Spinal Stability, LLC 104 Hensley Circle Austin, Texas 78738 USA 512-633-5313
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	MODULIF-A Anterior Lumbar Interbody Fusion System
Common Name	intervertebral body fusion device
Classification Name	Intervertebral body fusion device – lumbar
Class	II
Product Code	MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	InFix® Anterior Lumbar System, Zimmer Spine, (K132790)
Additional Predicate Devices	A-Wedge Anterior Interbody System, SpineWorks (K111166) Mojave Expandable Interbody System, K2M (K163364) Pathway ELIF, Custom Spine, Inc. (K143143)
Device Description	The Spinal Stability MODULIF-A is a modular interbody fusion cage intended for the treatment of degenerative disc disease in the lumbar spine used to provide structural stability in skeletally mature patients. The MODULIF-A device is composed of two endplates and a central spacer. The device may be implanted as a single construct via an anterior approach. The system is comprised of interbodies of various fixed heights and footprints to fit the anatomical needs of a wide variety of patients and multiple surgical approaches.
Materials	• Ti-6Al-4V Grade 23 per ASTM F136 • Ti-6Al-4V Grade 5 per ASTM F1472 • CP Titanium per ASTM F1580 • 316 L SST per ASTM A580

Intended Use	MODULIF-A is used to maintain disc space distraction and structural stability until fusion occurs in skeletally mature adults requiring lumbar interbody fusion.
Substantial Equivalence Claimed to Predicate Devices	The MODULIF-A is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	MODULIF-A is an interbody fusion device intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal procedure at the involved level(s). The device system is designed for use with supplemental fixation and with autogenous or allograft bone graft comprised of cancellous and / or corticocancellous bone graft to facilitate fusion. Patients should have six months of non-operative treatment prior to treatment with an interbody fusion cage. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device.
Summary of the technological characteristics compared to predicate	Intended Use The MODULIF-A and the predicate devices are all intended to be used to maintain adequate disc space until fusion occurs. Indications for Use All of the devices comply with the indications for use specified in 21 CFR section 888.3080 for cervical interbody fusion devices Material The MODULIF-A uses the same material as the predicate device. Design The MODULIF-A and the predicate are equivalent in terms of shape, material, and manufacturing process. Sizes The MODULIF-A and the predicates are equivalent in their dimensions. Strength The MODULIF-A has greater or equivalent strength values compared to other devices cleared for use in the lumbar spine.
Non-clinical Test Summary	The following analyses were conducted: ➢ Static and Dynamic Compression per ASTM F2077 ➢ Static Torsion per ASTM F2077 ➢ Static and Dynamic Compression-Shear per ASTM F2077 ➢ Subsidence per ASTM F2267 ➢ Expulsion ➢ Sterility validation per ISO 17665-1: 2006 ➢ Cleaning validation per AAMI TIR30 The results of these evaluations indicate that the MODULIF-A Anterior Lumbar Interbody Fusion System is equivalent to predicate devices.

Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Spinal Stability considers the MODULIF-A to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use