Osseus Fusion Systems, LLC
% J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

August 15, 2018

Re: K181347
Trade/Device Name: Aries® Lumbar Interbodies
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 18, 2018
Received: July 20, 2018

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/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)*

K181347

Device Name

Aries® Lumbar Interbodies

Indications for Use *(Describe)*

The Aries® Lumbar Interbodies (Aries®-TS, Aries®-TC, Aries®-O, Aries®-A, and Aries®-L) are interbody fusion devices intended for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Aries® Lumbar Interbodies are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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: Aries® Lumbar Interbodies

Date Prepared	July 18, 2018
Submitted By	Osseus Fusion Systems, LLC 2703 W. Mockingbird Ln., Ste. #102 Dallas, TX 75204 (888) 330-5960 Tele
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele jdwebb@orthomedix.net
Trade Name	Aries® Lumbar Interbodies
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	• EIT Cellular Titanium® TLIF Cages, EIT Emerging Implant Technologies, GmbH (K170503)
Secondary Predicate Devices	• CASCADIA™ Interbody System, K2M, Incorporated (K160547/K162264/ K172009/ K172941) • BAK/L Interbody Fusion System, Zimmer (P950002) • Oracle Cage System, Synthes (K072791) • ALEUTIAN® Anatomically-Narrow Oblique Interbody System, K2M, Incorporated (K082698/ K101302)
Reference Predicate Devices	• Ray Threaded Lumbar Fusion Cage, Stryker (P950019) • Brantigan I/F Cage, DePuy Spine, Inc (P960025) • Talos Intervertebral Body Fusion Devices, Meditech Spine, LLC (K090707 / K150788) • LDR Spine Cervical Interbody Fusion System, LDR Spine (K091088)
Device Description	The Aries® Lumbar Interbodies are interbody fusion devices used to provide structural stability in skeletally mature patients. The implants were developed for the substitution of the classical autogenous bone graft blocks. The cages assist to avoid complications related to the bone graft donation site (chronic pain, hematoma, infection, bone removal from the donor site making it impossible to remove bone again, quality of the iliac bone, accessing a healthy donor site that may become an unhealthy site, hernias by the incision). 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. Each interbody has an axial hole to allow grafting material to be placed inside of the interbody. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

Materials	3D-printed titanium (Ti-6Al-4V) per ASTM F3001
Intended Use	The Aries® Lumbar Interbodies (Aries®-TS, Aries®-TC, Aries®-O, Aries®-A, and Aries®-L) are 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 Aries® Lumbar Interbodies is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Aries® Lumbar Interbodies (Aries®-TS, Aries®-TC, Aries®-O, Aries®-A, and Aries®-L) are interbody fusion devices intended for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Aries® Lumbar Interbodies are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The Aries® Lumbar Interbodies and all the predicates have similar intended uses. <u>Materials</u> The Aries® Lumbar Interbodies is fabricated from the same material as the predicate device <u>Design Features/Functions</u> The Aries® Lumbar Interbodies and cited predicate devices share similar basic design features and functions. <u>Dimensions</u> The Aries® Lumbar Interbodies is dimensionally similar to cited predicate devices. <u>Sterilization</u> The Aries® Lumbar Interbodies is provided sterile and cited predicate devices are sterile for single use only. <u>Performance Specification</u> Mechanical testing confirmed the Aries® Lumbar Interbodies demonstrated equivalent performance to the cited predicate device under the same test conditions.
Non-clinical Test Summary	The following analyses were conducted: ➢ Static and Dynamic Compression per ASTM F2077 ➢ Static and Dynamic Torsion per ASTM F2077 ➢ Static and Dynamic Compression-Shear per ASTM F2077 ➢ Subsidence per ASTM F2267 ➢ Pyrogenicity was evaluated using the Limulus amebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device. The results of these evaluations indicate that the Aries® Lumbar Interbodies are equivalent to predicate devices.

Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osseus Fusion Systems considers the Aries® Lumbar Interbodies 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