January 7, 2019

Kalitec Medical, LLC
% J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K182210
Trade/Device Name: TiWAVE-L™ Porous Titanium Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 13, 2018
Received: August 15, 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,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182210

Device Name

TiWAVE-L™ Porous Titanium Lumbar Cage

Indications for Use *(Describe)*

The TiWAVE-L™ Porous Titanium Lumbar Cage is indicated 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-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). TiWAVE-L™ Porous Titanium Lumbar Cage implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and implanted via a transforaminal approach or an open posterior approach. The TiWAVE-L™ Porous Titanium Lumbar Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at 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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443-6740 EF

510(k) Summary
for the TiWAVE-L™ Porous Titanium Lumbar Cage

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

Date Prepared	December 6, 2018
Submitted by	Scott Winn Kalitec Medical, LLC 618 E. South Street, Suite 500 Orlando, FL 32801 407-545-2063 Tele 407-358-5441 Fax
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Secondary Contact	Keith Cannan 1890 W. CR 419, Suite 2000 Oviedo, FL 32765 407-545-2063 Tele 407-358-5441 Fax e-mail: kcannan@kalitecmed.com
Trade Name	TiWAVE-L™ Porous Titanium Lumbar Cage
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	NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody, HT Medical, LLC (K170318)
Additional Predicate Devices	Cascadia™ Interbody System, K2M, Inc. (K160125/ K162264/ K172009/ K172941/ K170318) BAK/L Interbody Fusion System, Zimmer (P950002) Brantigan I/F Cage, DePuy Spine, Inc. (P960025) InTess Lumbar Cage System, Kalitec Direct, LLC (K133815) InTess Cervical Cage System, Kalitec Direct, LLC (K123100)
Device Description	The TiWAVE-L Porous Titanium Lumbar Cages are lumbar intervertebral body fusion devices made from additive manufactured (AM) Titanium Grade 23 per ASTM F3001. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided sterile.
Materials	Implants are made from additive manufactured (AM) Titanium Grade 23 per ASTM F3001. System specific instruments are made from either stainless steel conforming to ASTM F899 or Ti6Al4V ELI titanium alloy conforming to ASTM F136.

Intended Use	Intervertebral body fusion devices indicated for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.
Substantial Equivalence Claimed to Predicate Devices	The TiWAVE-L Porous Titanium Lumbar Cage is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The TiWAVE-L Porous Titanium Lumbar Cage is indicated 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-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). TiWAVE-L Porous Titanium Lumbar Cage implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft implanted via a transforaminal approach or an open posterior approach. The TiWAVE-L Porous Titanium Lumbar Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The TiWAVE-L Porous Titanium Lumbar Cage and all the predicates have similar intended uses. <u>Materials</u> The TiWAVE-L Porous Titanium Lumbar Cage is composed of the same material as the predicate device. <u>Design Features/Functions</u> The TiWAVE-L Porous Titanium Lumbar Cage and cited predicate devices share similar basic design features and functions. <u>Dimensions</u> The TiWAVE-L Porous Titanium Lumbar Cage is dimensionally similar to cited predicate devices. <u>Sterilization</u> The TiWAVE-L Porous Titanium Lumbar Cage is provided sterile and cited predicate devices are packaged sterile for single use only. <u>Performance Specification</u> Mechanical testing confirmed the TiWAVE-L Porous Titanium Lumbar Cage demonstrated equivalent performance to the cited predicate device under the same test conditions.
Non-clinical Test Summary	The following tests were independently performed on the TiWAVE-L Porous Titanium Lumbar Cage to demonstrate substantial equivalence based on current industry standards: ➢ Static and dynamic axial compression (per ASTM F2077) ➢ Static torsion (per ASTM F2077) ➢ Static and dynamic compression shear (per ASTM F2077) ➢ Subsidence (per ASTM F2267) ➢ Static Expulsion (per ASTM draft standard F04.25.02.02) ➢ Bacterial Endotoxin (BET) The results of these evaluations indicate that the TiWAVE-L Porous Titanium Lumbar Cage is substantially equivalent to the predicate devices.
Clinical Test Summary	No clinical studies were performed.
Conclusions: Non-clinical and Clinical	Kalitec Medical considers the TiWAVE-L Porous Titanium Lumbar Cage system to be substantially 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. Based on the testing performed, it can be concluded that there are no new issues of safety or efficacy when comparing the subject device to the predicates.