Kalitec Direct, LLC
% Teresa Cherry
Cherry Tree Consulting
1230 Show Drive
Orlando, Florida 32828

June 14, 2018

Re: K180401
Trade/Device Name: TiWAVE-C™ Porous Titanium Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 15, 2018
Received: May 16, 2018

Dear Ms. Cherry:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Digitally signed
by 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)*
K180401

Device Name
TiWAVE-C™ Porous Titanium Cervical Cage

Indications for Use *(Describe)*
The TiWAVE-C™ Porous Titanium Cervical Cage is intended for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks of prior non-operative treatment prior to treatment with the device. The devices must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

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
for the TiWAVE-C™ Porous Titanium Cervical Cage

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

Date Prepared	Dec 15, 2017
Submitted by	Scott Winn Kalitec Direct, LLC 618 E. South Street, Suite 500 Orlando, FL 32801 407-545-2063 Tele 407-358-5441 Fax
Primary Contact	Teresa Cherry Cherry Tree Consulting 1230 Show Drive Orlando, FL 32828 407-252-3295 e-mail: Teresa@cherrytreequality.com
Secondary Contact	Keith Cannan 1890 W. CR 419, Suite 2000 Oviedo, FL 32765 407-545-2063 Tele 407-358-5441 Fax e-mail: quality@kalitecdirect.com
Trade Name	TiWAVE-C™ Porous Titanium Cervical Cage
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody K170318
Secondary Predicate Devices	Cascadia™ Interbody System K160125
Device Description	The TiWAVE-C™ Porous Titanium Cervical Cages are 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 17-4 H900 SS or 465 SS H950 conforming to ASTM F899
Intended Use	Intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.
Substantial Equivalence Claimed to Predicate Devices	The TiWAVE-C™ Porous Titanium Cervical 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-C™ Porous Titanium Cervical Cage is intended for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks of prior non-operative treatment prior to treatment with the device. The devices must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

Non-clinical Test Summary	The following tests were independently performed on the device to demonstrate safety based on current industry standards: • Static and dynamic axial compression (per ASTM F2077) • Static and dynamic torsion (per ASTM F2077) • Static compression shear (per ASTM F2077) • Subsidence (per ASTM F2267) • Static Expulsion The effectiveness of the gamma irradiation as a means of sterilization was validated using AAMI/ANSI/ISO 11137-2 – method VD_{max}^{25}. This included: • Bioburden recovery factor testing • Bacteriostasis and fungistasis • Bioburden • Verification dose • Sterility testing of the verification dose sample The effectiveness of the final ultrasonic cleaning procedure for gamma sterilization included the following process qualifications: • Visual verification • Bioburden testing • Cytotoxicity testing • UV/Vis testing • Total organic carbon (TOC) • Bacterial Endotoxin (LAL) The effectiveness of the packaging and shipping of sterile product included the following process qualifications: • Shipping testing • Peel strength testing • Bubble emission testing • Integrity inspections The results of these evaluations indicate that the TiWAVE-C™ Porous Titanium Cervical Cage is equivalent to predicate device.
Clinical Test Summary	No clinical studies were performed.
Conclusions: Non-clinical and Clinical	Kalitec Direct, LLC considers the TiWAVE-C™ Porous Titanium Cervical Cage 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. 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.