EIT Emerging Implant Technologies GmbH
Barbara Wirth
Director Quality Assurance and Regulatory Affairs
Eisenbahnstrasse 84
78573 Wurmlingen, Germany

February 4, 2019

Re: K183447
Trade/Device Name: EIT Cellular Titanium® Lumbar Cage - T/PLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 11, 2018
Received: December 12, 2018

Dear Ms. Wirth:

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

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)*
K183447

Device Name
EIT Cellular Titanium® Lumbar Cage - T/PLIF

Indications for Use *(Describe)*
The EIT Cellular Titanium® Lumbar Cages - T/PLIF in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

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

Device Trade Name	EIT Cellular Titanium® Lumbar Cage - T/PLIF
Manufacturer	EIT Emerging Implant Technologies GmbH Eisenbahnstrasse 84 78573 Wurmlingen, Germany Phone: +49 7461 1716900
Contact	Barbara Wirth EIT Emerging Implant Technologies GmbH Eisenbahnstrasse 84 78573 Wurmlingen, Germany
Date Prepared	January 22, 2019
Classifications	21 CFR §888.3080, Intervertebral body fusion device
Class	II
Product Codes	MAX

Indications for Use

The EIT Cellular Titanium® Lumbar Cages - T/PLIF in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 –S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Device Description

The EIT Cellular Titanium Lumbar Cages - T/PLIF are intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the lumbar spine (L2-S1). Multiple footprints, heights and lordotic angle cages are offered to accommodate varying patient anatomical and physiological requirements. The EIT Cellular Titanium Lumbar Cages - T/PLIF are made from Titanium-6Aluminum-4Vanadium ELI ASTM F3001 through an additive manufacturing process. The design contains solid structures and porous structures formed as a diamond mesh. The hollow geometry of the cages allows them to be packed with autogenous bone graft.

No changes to the design or manufacture of the EIT Cellular Titanium Lumbar Cages - PLIF previously cleared in K172888 are proposed with this submission. The focus of this premarket notification is to expand the labeling of the previously cleared EIT Cellular Titanium Lumbar Cages - PLIF to include a transforaminal lumbar interbody fusion (TLIF) surgical approach and name it accordingly (EIT Cellular Titanium Lumbar Cages - T/PLIF). Additionally, the raw material specification for the cage is corrected from ASTM F136 (Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications) to ASTM F3001 (Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion) with this submission.

Primary Predicate Device

Tritanium® PL Cage (K181014)

Additional Predicate Devices

EIT Cellular Titanium Lumbar Cage - PLIF (K172888)
EIT Cellular Titanium Lumbar Cage - PLIF (K170503)

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The Tritanium PL Cages and the EIT Cellular Titanium Lumbar Cages - T/PLIF share the indication of DDD at one or two contiguous spinal levels from L2 to S1. Additionally, both systems are indicated for use with supplemental fixation and autogenous bone graft. Both cages are rectangular box shaped with a bulleted nose and the respective cage size offerings are similar. The Tritanium PL surgical technique includes a TLIF surgical approach in addition to a PLIF surgical approach.

Materials

The Tritanium PL Cages are constructed from Titanium alloy (Titanium-6Aluminum- 4vanadium) conforming to ASTM F1472-08. The raw material specification for the EIT Cellular Titanium Lumbar Cage - T/PLIF cage is corrected from ASTM F136 (Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications) to ASTM F3001 (Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion) with this submission. There is no change to the actual raw material, only a correction to the standard referenced from that for a wrought form of the material like a bar or sheet to that for the powder.

Performance Testing Summary

A technical rationale comparing the current surgical technique with that proposed (a TLIF surgical approach) was supplied.

Conclusion

The EIT Cellular Titanium Lumbar Cages - T/PLIF are substantially equivalent to previously cleared devices with respect to indications for use, design, function, materials, and performance.