Dear Justin Eggleton:

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
Indications for Use

510(k) Number (if known)
K181644

Device Name
EIT Cellular Titanium® Lumbar Cage LLIF

Indications for Use (Describe)

EIT Cellular Titanium® Lumbar Cage LLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTAFF@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) Summary

Device Trade Name: EIT Cellular Titanium® Lumbar Cage LLIF

Manufacturer: EIT Emerging Implant Technologies GmbH
Eisenbahnstrasse 84
78573 Wurmlingen, Germany
Phone: +49 7461 1716900

Contact: Mrs. Barbara Wirth
EIT Emerging Implant Technologies GmbH
Eisenbahnstrasse 84
78573 Wurmlingen, Germany

Prepared by: Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
jeggleton@mcra.com

Date Prepared: October 12, 2018

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Indications for Use:
EIT Cellular Titanium® Lumbar Cage LLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for the EIT Cellular Titanium® Lumbar Cage LLIF to be added to the EIT Spine line of lumbar interbody cages. The EIT Cellular Titanium® Lumbar Cage LLIF is used to restore intervertebral height
and to facilitate intervertebral body fusion in the spine using an LLIF (Lateral Lumbar Intervertebral Fusion) approach with autogenous bone graft and/or allogenic bone graft materials. The EIT Cellular Titanium® Lumbar Cage LLIF is intended to be used from L2-S1 in patients with DDD and up to Grade I spondylolisthesis or retrolisthesis at one or two contiguous levels. The device is intended to be used alongside supplemental spinal fixation, either applied anteriorly or posteriorly (e.g., using posterior pedicle screws).

The EIT Cellular Titanium® Lumbar Cage LLIF is made from Ti-6Al-4V ELI (ASTM F3001) by an additive manufacturing process. The design contains solid structures and porous structures. The hollow geometry of the implants allows the cage to be packed with autogenous bone graft.

**Primary Predicate Device:**
The EIT Cellular Titanium® Lumbar Cage LLIF is substantially equivalent to the SPINEART JULIET® LL Lateral Lumbar Cage in device indications, surgical approach, design, and performance.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device Name</th>
<th>K-Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPINEART</td>
<td>JULIET® LL Lateral Lumbar Cage</td>
<td>K161888</td>
</tr>
</tbody>
</table>

**Additional Predicate Devices:**
The EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages (EIT Emerging Implant Technologies, GmbH) (K172888) are substantially equivalent to the subject device with respect to indications, design, additive manufacturing process, and performance.

**Performance Testing Summary:**
The testing of the EIT Cellular Titanium® Lumbar Cage LLIF and cage-dedicated instruments includes:

- Mechanical testing per ASTM F2077 and ASTM F2267: Static compression, static compression-shear, dynamic compression, dynamic compression-shear, expulsion, and subsidence
- Biocompatibility rationale comparing the materials used to manufacture the device and instruments with confirmed biocompatibility profiles per ISO 10993.
- MRI Safety Testing per ASTM F2052-15, ASTM F2213-06, and ASTM F2182-11a

The subject device, the EIT Cellular Titanium® Lumbar Cage LLIF, can be used with autogenous bone graft and/or allogenic bone graft materials to facilitate fusion. Both the primary and secondary predicate devices are indicated for use only with autogenous bone graft. As a result of the inclusion of allogenic bone graft materials in this submission, a comprehensive clinical literature review was performed to show the clinical performance of allograft bone materials for lumbar interbody fusion.
**Substantial Equivalence:**
The subject devices were demonstrated to be substantially equivalent to predicates cited in the table above with respect to indications, design, materials, function, manufacturing, and performance. Pyrogenicity testing has been completed on the “worst case” EIT lumbar cages. Equivalence has been established to these EIT lumbar cages and the EIT Cellular Titanium® Lumbar Cage LLIF subject device cages do not introduce a new “worst case” cage. As a result, the pyrogenicity testing completed for the EIT lumbar cage family is applicable to the EIT Cellular Titanium® Lumbar Cage LLIF devices.

**Conclusion:**
The EIT Cellular Titanium® Lumbar Cage LLIF is substantially equivalent to the cited predicate devices with respect to its indications for use, design, function, materials, and performance.