



EIT Emerging Implant Technologies GmbH  
% Mr. Justin Eggleton  
Senior Director, Spine Regulatory Affairs  
Musculoskeletal Clinical Regulatory Advisors, LLC  
1050 K Street NW, 10th Floor  
Washington, District of Columbia 20005

December 15, 2017

Re: K172888

Trade/Device Name: EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages,  
EIT Cellular Titanium® TLIF Cages, EIT Cellular Titanium® ALIF Cages  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX, ODP  
Dated: December 6, 2017  
Received: December 7, 2017

Dear Mr. 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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K172888

Device Name

EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, EIT Cellular Titanium® ALIF Cages

Indications for Use (Describe)

### EIT Cellular Titanium® Cervical Cages

The EIT Cellular Titanium® Cervical Cages are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium® Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The EIT Cellular Titanium® Cervical Cages is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

### EIT Cellular Titanium® PLIF Cages

The EIT Cellular Titanium® PLIF Cages 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 non-operative treatment prior to treatment with the devices.

### EIT Cellular Titanium® TLIF Cages

The EIT Cellular Titanium® TLIF Cages 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 non-operative treatment prior to treatment with the devices.

### EIT Cellular Titanium® ALIF Cages

The EIT Cellular Titanium® ALIF Cages 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 non-operative 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® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages

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

**Contact:** Ms. Barbara Wirth  
EIT Emerging Implant Technologies GmbH  
Eisenbahnstrasse 84  
78573 Wurmlingen, Germany  
Barbara.wirth@eit-spine.de

**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](mailto:jeggleton@mcra.com)

**Date Prepared:** November 30, 2017

**Classifications:** 21 CFR §888.3080, Intervertebral body fusion device

**Class:** II

**Product Codes:** MAX, ODP

### Indications for Use:

#### EIT Cellular Titanium® Cervical Cages

The EIT Cellular Titanium® Cervical Cages are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium® Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The EIT Cellular Titanium® Cervical Cages is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

### EIT Cellular Titanium® PLIF Cages

The EIT Cellular Titanium® PLIF Cages 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 non-operative treatment prior to treatment with the devices.

### EIT Cellular Titanium® TLIF Cages

The EIT Cellular Titanium® TLIF Cages 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 non-operative treatment prior to treatment with the devices.

### EIT Cellular Titanium® ALIF Cages

The EIT Cellular Titanium® ALIF Cages 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 non-operative treatment prior to treatment with the devices.

### **Device Description:**

The purpose of this 510(k) was to update the indications for use to include use at multiple levels (e.g., up to 4 levels) for the EIT Cellular Titanium® Cervical Cages as well as other miscellaneous labeling updates.

The EIT Cellular Titanium® Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the spine. The EIT Cellular Titanium® Cages differentiated in Lumbar cages (L2-S1) and Cervical Cages (C2-T1). The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g., using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The EIT Cellular Titanium® Cages are made from Ti-6Al-4V ELI ASTM F136 with an additive manufacturing process. The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Three different types of Lumbar Cages are included in the portfolio. Each cage type has the same intended use, but is designed for a different surgical approach; ALIF (Anterior Lumbar Intervertebral Fusion Cage), PLIF (Posterior Lumbar Intervertebral Fusion Cage) and TLIF (Transforaminal Lumbar Intervertebral Fusion Cage). One type of Cervical Cage, CIF (Cervical Intervertebral Fusion Cage) is included in the portfolio. Each cage type is supplied sterile and is available in a variety of heights, footprints and lordosis angles to accommodate patient anatomy.

**Predicate Device:**

The EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages are substantially equivalent to the predicates previously cleared with respect to indications, design, function, and materials, as outlined below.

**Table 1: Primary Predicate Devices**

Manufacturer	Device Name	K-Number
NuVasive®, Inc.	NuVasive® CoRoent® Small Interbody System	K163491

Additional Predicates: EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages (EIT Emerging Implant Technologies, GmbH) (K170503)

**Performance Testing Summary:**

A comprehensive, clinical literature review was provided to investigate the risks and benefits associated with the use of the EIT Cellular Titanium® Cervical Cages in multilevel cervical procedures. Additional MR-Safety testing was performed in accordance with ASTM F2052-15, ASTM F2213-06(2011), ASTM F2119-07(2013), and ASTM F2182-11a in support of labeling modifications.

**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/or performance.

**Conclusion:**

The EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages are substantially equivalent to previously cleared devices with respect to its indications for use, design, function, materials, and performance.