



Food and Drug Administration  
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July 11, 2017

EIT Emerging Implant Technologies, GmbH  
% Justin Eggleton  
Director, Spine Regulatory Affairs  
Musculoskeletal Clinical Regulatory Advisers, LLC  
1050 K Street NW, 10th Floor  
Washington, District of Columbia 20001

Re: K170503

Trade/Device Name: EIT Cellular Titanium® Cervical Cage, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and 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: June 8, 2017

Received: June 9, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Vincent J. Devlin -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)

K170503

Device Name

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

Indications for Use (Describe)

EIT Cellular Titanium® Cervical Cage

The EIT Cellular Titanium® Cervical Cages are intervertebral body fusion devices indicated for use with autograft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non-operative treatment. 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.

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 nonoperative 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 nonoperative 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 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® Cervical Cage, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages

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**Date Prepared:** June 7, 2017

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

**Class:** II

**Product Codes:** MAX, ODP

### Indications For Use:

#### EIT Cellular Titanium® Cervical Cage

The EIT Cellular Titanium® Cervical Cages are intervertebral body fusion devices indicated for use with autograft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non-operative treatment. 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.

### 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 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 Cage, 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 Device**

<b>Manufacturer</b>	<b>Device Name</b>	<b>K-Number</b>
Ortho Development	Vusion CS+	K122588

Additional Predicates: Scient’X Tribeca Cage (K080588)

CoAlign AccuLIF (K093669, K112095)

4Web PLIF STS, TLIF STS and OLIF STS (Spine Truss System) (K143258)

Precision Spine ShurFit® PLIF Interbody Cage (K092193)

**Performance Testing Summary:**

The worst case devices were subjected to mechanical testing. Testing included static compression, static compression-shear, dynamic compression, dynamic compression-shear, torsion, dynamic torsion, expulsion, and subsidence per ASTM F2077-14 and F2267-04. Additional bacterial endotoxin testing was performed as part of the sterilization validation. The results demonstrate that the devices are substantially equivalent to the predicate devices.

**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 Cage, 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.