



July 15, 2020

EIT Emerging Implant Technologies GmbH
% Ms. Christine Cahillane
Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Dr.
Raynham, MA 02767 USA

Re: K201605

Trade/Device Name: EIT Cellular Titanium[®] Cervical Cage, EIT Cellular Titanium[®] ALIF Cage, EIT Cellular Titanium[®] TLIF Cage, EIT Cellular Titanium[®] LLIF Cage, EIT Cellular Titanium[®] T/PLIF Cage

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: MAX, ODP

Dated: June 12, 2020

Received: June 15, 2020

Dear Ms. Cahillane:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K201605

Device Name

EIT Cellular Titanium® Cervical Cage, EIT Cellular Titanium® ALIF Cage,
EIT Cellular Titanium® TLIF Cage, EIT Cellular Titanium® LLIF Cage,
EIT Cellular Titanium® T/PLIF Cage

Indications for Use (Describe)

EIT Cellular Titanium® Cervical Cage

The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features 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. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

EIT Cellular Titanium® ALIF Cage

The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features 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 Cage

The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features 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® LLIF Cage

The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are 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 I 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.

EIT Cellular Titanium® T/PLIF Cage

The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features 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)

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K201605 - 510(k) Summary

A. Submitter Information

Manufacturer:

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Contact:

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On behalf of EIT Emerging Implant Technologies GmbH
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Raynham, MA 02767

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508-828-3064

Email Address:

ccahilla@its.jnj.com

B. Date Prepared

June 23, 2020

C. Device Name

EIT Cellular Titanium® Cervical Cage
EIT Cellular Titanium® ALIF Cage
EIT Cellular Titanium® TLIF Cage
EIT Cellular Titanium® LLIF Cage
EIT Cellular Titanium® T/PLIF Cage

Classification:

21 CFR §888.3080, Intervertebral body fusion device

Regulatory Class:

II

Product Codes:

ODP - Intervertebral Fusion Device with Bone Graft,
Cervical
MAX - Intervertebral Fusion Device with Bone Graft,
Lumbar

D. Predicate Device Names

EIT Cellular Titanium® Cervical Cage (K172888)
EIT Cellular Titanium® ALIF Cage (K172888)
EIT Cellular Titanium® TLIF Cage (K172888)
EIT Cellular Titanium® LLIF Cage (K181644)
EIT Cellular Titanium® T/PLIF Cage (K183447)



E. Device Description

The EIT Cellular Titanium® Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. 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 conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft, and two of the systems allow for the cages to be packed with allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft.

The 3D Printed EIT Cellular Titanium® Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

F. Intended Uses

EIT Cellular Titanium® Cervical Cage

The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features 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. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

EIT Cellular Titanium® ALIF Cage

The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features 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 Cage

The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features 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® LLIF Cage

The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features 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.

EIT Cellular Titanium® T/PLIF Cage

The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features 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.

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

The fundamental scientific technology of the subject devices remains unchanged from the predicate devices. There is no change to the intended use of the product from the predicate devices. This submission presents an expansion of the device description within the labeling supported by established methods for surface analysis. There has been no change to the design or additive manufacturing process of the EIT Cellular Titanium Cervical or Lumbar Cages previously cleared in K172888, K181644 and K183447.

H. Materials

The EIT Cellular Titanium Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001.

I. Performance Testing Summary

Performance data remains unchanged for the subject devices as compared to the predicate devices.

J. Conclusion

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