icotec AG
% Justin Eggleton
VP, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Steet NW
Washington, District of Columbia 20001

April 5, 2024

Re: K232792
Trade/Device Name: icotec Interbody Cage System (icotec Cervical Cage, icotec PLIF Lumbar Cage, icotec ETurn™ TLIF Lumbar Cage)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: March 4, 2024
Received: March 4, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.04.05 13:12:52 -04'00'

for

Brent Showalter, Ph.D.
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232792

Device Name
icotec Interbody Cage System (icotec Cervical Cage, icotec PLIF Lumbar Cage, icotec ETurn® TLIF Lumbar Cage)

Indications for Use *(Describe)*
icotec Cervical Cage

The icotec Cervical Cage is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with degenerative cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone.

This device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

When used with the icotec Anterior Cervical Plate System, the icotec Cervical Cage is intended to stabilize the cervical spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

icotec PLIF Cage

The icotec PLIF Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended to be used with autograft.

When used with the VADER® Pedicle System, the icotec PLIF Cage is intended to stabilize the lumbar spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

icotec ETurn® TLIF Cage

The icotec ETurn® TLIF Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended to be used with autograft.

When used with the VADER® Pedicle System, the icotec ETurn TLIF Cage is intended to stabilize the lumbar spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

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: icotec Interbody Cage System (icotec Cervical Cage, icotec PLIF Lumbar Cage, icotec ETurn® TLIF Lumbar Cage)

Manufacturer:
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Date Prepared: April 1, 2024

Classification: 21 CFR §888.3080: Intervertebral body fusion device

Class: II

Product Code: ODP, MAX

Primary Predicate: icotec Interbody Cage System (K192897, K172480)

Reference Device: icotec VADER® Pedicle System (K232628)

Indications for Use:

icotec Cervical Cage

The icotec Cervical Cage is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with degenerative cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis,

cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone.

This device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

When used with the icotec Anterior Cervical Plate System, the icotec Cervical Cage is intended to stabilize the cervical spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

icotec PLIF Cage

The icotec PLIF Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended to be used with autograft.

When used with the VADER® Pedicle System, the icotec PLIF Cage is intended to stabilize the lumbar spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

icotec ETurn® TLIF Cage

The icotec ETurn® TLIF Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended to be used with autograft.

When used with the VADER® Pedicle System, the icotec ETurn TLIF Cage is intended to stabilize the lumbar spinal column as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

Device Description:
The icotec Interbody Cage System (i.e., icotec Cervical Cage, icotec PLIF Cage, and icotec ETurn® TLIF Cage) is an interbody cage system designed to restore the intervertebral height and to facilitate intervertebral body fusion of the spine. The devices are manufactured from high strength carbon fiber reinforced polyetheretherketone (Carbon/PEEK, BlackArmor®) and incorporate a rough titanium coating. The devices are intended to be used with supplemental spinal fixation.

There is one type of cervical cage and two lumbar cages (i.e., PLIF and ETurn® TLIF) included in this portfolio. Each cage is provided sterile and is available in an assortment of heights, footprints, and/or lordosis angles to accommodate patient anatomy.

Predicate Devices:
The icotec Interbody Cage System is substantially equivalent to the primary predicate device cited on the previous page with respect to indications, design, function, and performance.

Performance Testing:
The clinical data provided supports a substantially equivalent safety and effectiveness profile for the use of intervertebral body fusion devices for the indications for use. However, the provided clinical data did not support that the specific material or unique technological characteristics of the subject device components provides additional benefit relative to other intervertebral body fusion devices for the indications for use related to infection.

Conclusion:
The purpose of the traditional 510(k) is to receive regulatory clearance to introduce the icotec Interbody Cage System to interstate commerce for expanded indications that describe the spinal infection patient population. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.