May 17, 2018

icotec ag
% Samuel Pollard
Senior Associate Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Affairs
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K172480
Trade/Device Name: icotec Interbody Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: April 20, 2018
Received: April 20, 2018

Dear Samuel Pollard:

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) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172480

Device Name
icotec Interbody Cage System

Indications for Use *(Describe)*

icotec Cervical Cage

The icotec Cervical Cage is intended for spinal fusion procedures at one level (C2-Tl) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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.

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.

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.

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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1 510(k) Summary

Device Trade Name: icotec Interbody Cage System

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Date Prepared: August 4, 2017

Classification: 21 CFR §888.3080

Common Name: Intervertebral body fusion device

Class: II

Product Code: ODP, MAX

Primary Predicates: Cervical: Ortho Development Vusion CS+ (K122588)
Lumbar: Scient'X Tribeca Cage (K080588)

Additional Predicates: icotec ETurn Spinal Implant (K100305), Kimba Cage (K111792), Precision Spine Shurfit PLIF Interbody Cage (K092193) and CoAlign AccuLIF (K093669, K112095), Zimmer TM-S Fusion Device (K111119)

Indications for Use:

Cervical

The icotec Cervical Cage is intended for spinal fusion procedures at one level (C2-Tl) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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.

PLIF

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.

TLIF

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.

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 porous 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 lordosis angles to accommodate patient anatomy.

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

Preclinical Testing:
The non-clinical tests performed by the company include static and dynamic compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267), and expulsion testing of the worst case construct. The results of the performed tests demonstrate that the icotec Interbody Cage System is substantially equivalent to legally marketed predicate devices.

Conclusion:
The purpose of the traditional 510(k) is to receive regulatory clearance to introduce the icotec Interbody Cage System to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate devices.