March 20, 2020

icotec ag
% Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K192897
Trade/Device Name: icotec Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 13, 2020
Received: February 13, 2020

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. 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 L. Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192897

Device Name
icotec Cervical Cage

Indications for Use *(Describe)*

The icotec Cervical Cage is intended for spinal fusion procedures at one or more levels (C2-Tl) 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name: icotec Cervical Cage

Manufacturer:
icotec ag
Industriestrasse 12
9450 Altstätten
Switzerland

Contact:
Ms. Marina Hess
CQO/Management Representative
icotec ag
Industriestrasse 12
9450 Altstaetten, Switzerland
Phone: +41 71 757.0024
Fax: +41 71 757.0001
marina.hess@icotec.ch

Prepared by:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
jeggleton@mcra.com

Date Prepared: February 4, 2020

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: ODP

Indications for Use:
The icotec Cervical Cage is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with 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.

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for an expansion of the indications for use of the previously cleared icotec Cervical Cage to be used in multiple levels. The subject 510(k) also proposes to add a lordotic version of the previously cleared icotec Cervical Cage.

The icotec Cervical Cage is an interbody cage system designed to restore the intervertebral height and to facilitate intervertebral body fusion of the cervical spine. The devices are manufactured from high strength carbon fiber reinforced polyetheretherketone (Carbon/PEEK, BlackArmor®) and incorporate a Ti-iT® rough CP-titanium coating. The devices are intended to be used with supplemental spinal fixation. Each cage is provided sterile and is available in an assortment of heights, footprints, and lordosis angles to accommodate patient anatomy.

Primary Predicate Device:
The icotec Cervical Cage is substantially equivalent to the icotec Interbody Cage System in intended use, design, and performance.

Table 1. Primary Predicate Device

Manufacturer	Device Name	K-Number
icotec	icotec Interbody Cage System	K172480

Additional Predicate Device:
The Tyber Medical PT Interbody Spacer System (K182284) is substantially equivalent to the subject device with respect to indications and design.

Performance Testing Summary:
Benchtop mechanical testing of the icotec Cervical Cage was performed in K172480 and applies to the subject device. The benchtop mechanical testing includes the following:

- Mechanical testing per ASTM F2077 and ASTM F2267: Static axial compression, dynamic axial compression, static compression-shear, dynamic compression-shear, static torsion, dynamic torsion, expulsion, subsidence.
- Wear particle analysis as per ASTM F1877
- Coating characterization and performance testing as per ISO 13179, ASTM F1160, ASTM F1044, ASTM F1147, and ASTM F1978

Additionally, to support the inclusion of the lordotic version of the cervical cages, a risk analysis and expulsion testing was performed. To support the expansion of indications for use in multiple levels of the cervical spine, a comprehensive clinical literature review was performed to show the clinical performance and success of representative cervical cages in 2 or more levels of the cervical spine.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to predicates cited in the table above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
The icotec Cervical Cage is substantially equivalent to the cited predicate devices with respect to its indications for use, design, function, materials, and performance.