May 17, 2024

Icotec AG
% Justin Eggleton
VP, Head of Musculoskeletal Regulatory Affairs
Mcra, LLC.
803 7th Street NW, 3rd floor
Washington, District of Columbia 20001

Re: K233215
Trade/Device Name: icotec Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 19, 2024
Received: April 19, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K233215

Device Name
icotec Anterior Cervical Plate System

Indications for Use *(Describe)*
The icotec Anterior Cervical Plate System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine (C2-T1) in whom life expectancy is of insufficient duration to permit achievement of fusion.

When used with the icotec Cervical Cage or the KONG®-C VBR System, the icotec Anterior Cervical Plate System is intended to stabilize the cervical (from C2 to T1) spine 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.

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

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510(k) Summary

Device Trade Name: icotec Anterior Cervical Plate System

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Contact:
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Date Prepared: May 15, 2024

Classifications: 21 CFR §888.3060, Spinal intervertebral body fixation orthosis

Class: II

Product Codes: KWQ

Primary Predicate: icotec Anterior Cervical Plate System (K201587)

Reference Device: icotec VADER® Pedicle System (K232628)

Indications For Use:
The icotec Anterior Cervical Plate System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine (C2-T1) in whom life expectancy is of insufficient duration to permit achievement of fusion.

When used with the icotec Cervical Cage or the KONG®-C VBR System, the icotec Anterior Cervical Plate System is intended to stabilize the cervical (from C2 to T1) spine 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 Anterior Cervical Plate System consists of plates and screws intended for use in anterior cervical fixation from C2 to T1. The system is developed to allow for conventional ventral approaches to the cervical spine. The devices are manufactured from high strength carbon fiber reinforced polyetheretherketone (Carbon/PEEK, BlackArmor®) and incorporate tantalum markers per ASTM F560.

The icotec Anterior Cervical Plate System is available in various plate lengths and with self-tapping screws for the specific adaption to the patient's anatomy. The icotec Anterior Cervical Plates are 18 mm in width and come as 1- to 4-segmental implants with lengths ranging from 21 up to 94 mm. The plates are precontoured to fit patient anatomy. The screw holes in the plates are conical and threaded.

The icotec Anterior Cervical Plate System self-tapping screws are available in diameters of 4.0 and 4.25 mm with lengths of 13 and 15 mm. The fully threaded bone screws have threaded conical heads to firmly lock into the plate. The conical threaded screw heads are designed to block pullout while screw angulation in the cranial direction prevents screws from penetrating through the lower end plate of the vertebral body.

Predicate Device:
The icotec Anterior Cervical Plate System is substantially equivalent to the primary predicate device cited on the previous page with respect to indications, design, function, and performance.

Performance Testing Summary:
The clinical data provided supports a substantially equivalent safety and effectiveness profile for the use of anterior cervical plate 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 anterior cervical plate devices for the indications for use related to infection.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate device (K201587) with respect to indications for use, intended use, design, and performance.

Non-clinical testing data and clinical data demonstrate the performance of the subject device is substantially equivalent to that of the predicate device, and support the performance of the subject device in its expanded indications for use.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in identical materials and are sterilized using identical methods. The data included

in this submission demonstrate that the icotec Anterior Cervical Plate System is substantially equivalent to the predicate devices listed above.