October 15, 2020

icotec ag
℅ Margeaux Rogers
Associate Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K201587
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: September 18, 2020
Received: September 18, 2020

Dear Margeaux Rogers:

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,

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201587

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.

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 Anterior Cervical Plate System

Manufacturer:
icotec ag
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Switzerland
www.icotec-medical.com
Phone: +41 71 757.0000

Contact:
Ms. Marina Hess
CQO/Management Representative
icotec ag

Prepared by:
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Date Prepared: September 18th, 2020

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

Class: II

Product Codes: KWQ

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.

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 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 18mm in width and come as 1- to 4-segmental implants with lengths ranging from 21

up to 94mm. The plates are precontoured to better fit patient anatomy. The screw holes in the plates are conical and threaded.

The icotec ACP self-tapping screws are available in diameters of 4.0 and 4.25mm with lengths of 13 and 15mm. 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.

Primary Predicate Devices:
The icotec Anterior Cervical Plate System is substantially equivalent in device indications, design, and performance to the following primary predicate device.

- Aesculap, Inc. (AIS) ABC2 Cervical Plating System (K050813)

Additional Predicate Devices:
The following additional predicate devices are presented to further demonstrate substantial equivalence since these devices contribute incremental benefit to the substantial equivalence profile with the device indications, design, mechanical performance, and clinical performance:

- EBI VueLock™ Anterior Cervical Plate System (K023133)
- Synthes Spine Anterior CSLP System (K030866)

The following reference device is substantially equivalent to the subject device with respect to materials and manufacturing technology and methods:

- VADER®one Pedicle System MIS and Lightmore® Pedicle System 6.0 (K190545, K193423)

Performance Testing Summary:
The testing of the icotec Anterior Cervical Plate System includes:

- Static compression bending, static torsion and dynamic compression bending per ASTM F1717
- Biocompatibility Assessment
- Clinical Data

Substantial Equivalence:
The subject devices were demonstrated to be substantially equivalent to predicates cited above with respect to indications, design, materials, function, manufacturing, and performance. The non-clinical tests performed by the company, including static compression, static torsion and dynamic compression per ASTM F1717, met the pre-defined acceptance criteria. The results of the performed tests demonstrate that the icotec Anterior Cervical Plate System is substantially equivalent to the legally marketed predicate devices.

Conclusion:

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