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

April 4, 2024

Re: K232790
Trade/Device Name: KONG®-TL VBR System and KONG® C VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: March 5, 2024
Received: March 5, 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: 2024.04.04 13:33:57 -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

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)*
K232790

Device Name
KONG®-TL VBR System and KONG®-C VBR System

Indications for Use *(Describe)*
KONG®-TL VBR System

KONG®-TL VBR System devices are intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). When used in the thoracolumbar spine, the KONG®-TL VBR System is intended to be used with FDA-cleared supplemental fixation appropriate for the implanted level, including icotec Pedicle Screw Systems. These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used with the VADER® Pedicle System, the KONG®-TL VBR System is intended to stabilize the thoracic and/or lumbar 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.

KONG®-C VBR System

KONG®-C VBR System devices are intended for use in the cervical spine (from C2 to T1) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. KONG®-C VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used with the icotec Anterior Cervical Plate System, the KONG®-C VBR 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:	KONG®-C VBR System and KONG®-TL VBR System
Manufacturer:	icotec ag Industriestrasse 12 9450 Altstätten Switzerland www.icotec-medical.com Phone: +41 71 757.0000
Contact:	Ms. Marina Hess CQO/Management Representative icotec ag
Prepared by:	Mr. Justin Eggleton Vice President, Head of Musculoskeletal Regulatory Affairs MCRA, LLC 803 7th Street NW Washington, DC 20001 jeggleton@mcra.com
Date Prepared:	April 1, 2024
Classifications:	21 CFR §888.3060, Spinal intervertebral body fixation orthosis
Class:	II
Product Codes:	MQP, PLR
Primary Predicate:	KONG®-TL VBR System and KONG®-C VBR System (K200235)
Reference Device:	icotec VADER® Pedicle System (K232628)

Indications For Use:

KONG®-TL VBR System

KONG®-TL VBR System devices are intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). When used in the thoracolumbar spine, the KONG®-TL VBR System is intended to be used with FDA-cleared supplemental fixation appropriate for the implanted level, including icotec Pedicle Screw Systems. These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used with the VADER® Pedicle System, the KONG®-TL VBR System is intended to stabilize the thoracic and/or lumbar 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.

KONG®-C VBR System

KONG®-C VBR System devices are intended for use in the cervical spine (from C2 to T1) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. KONG®-C VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used with the icotec Anterior Cervical Plate System, the KONG®-C VBR 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:

KONG®-TL VBR System

The KONG®-TL VBR System is a vertebral body replacement system for anterior stabilization of the thoracic and lumbar spine. This device serves as a replacement for vertebral bodies in tumorous and traumatic diseases which lead to instabilities in the anterior support or compression of neural structures or diseases that make an infection repair necessary. The KONG®-TL VBR System is intended for use with an additional dorsal or anterolateral fixation system (e.g., icotec Pedicle System). The KONG®-TL VBR System is a modular design featuring an expandable body, extensions, and end plates with various heights, widths, and angles. The system consists of expandable body structures that range in height from 19 to 96 mm, have a diameter of 19 mm and surface treads/spikes on its cranial and caudal end plate surfaces that serve to guide and anchor the implant. The system also consists of rectangular and round end plate configurations. The end plate round configuration has a geometry that ranges from 0°, 4°, 8° and 12° and size that ranges from 26 to 43 mm. The end plate rectangular configuration has geometry that ranges from 0°, 4°, 8° and 12° and size that ranges from 33 to 52 mm. The end plates are locked with a screw onto the main body. The tread surfaces and spikes help to improve primary fixation stability of the end plates. The large contact surface of the end plates reduces the risk of migration. The screw for fixation of the end plates to the body has a length of 6 mm and a thread size of M8.

The KONG®-TL VBR System is made of BlackArmor® material, a carbon fiber reinforced polyetheretherketone (Carbon/PEEK) composite. Due to the excellent biocompatibility and material properties, Carbon/PEEK has been in clinical use in spine surgery for more than 20 years world-wide. The BlackArmor® material is a combination of continuous, high strength carbon fiber-reinforced PEEK and icotec's composite flow molding (CFM) process. The result is a non-metallic implant component with an interwoven 3D fiber architecture that provides strength and endurance. BlackArmor® is radiolucent in all diagnostic imaging modes (MRI, CT and X-ray) and will therefore not create imaging artifacts. Embedded tantalum markers (per ASTM F560) ensure the required radiologic visibility of the implant during surgery and follow-up. The KONG®-TL VBR System incorporates a rough cp-titanium coating (per ASTM F1580), designed to improve direct bone apposition.

The partially hollow geometry of the implants (endplates and extension) allows them to be packed with bone graft. The implants are supplied sterile and are available in a variety of heights, footprints and anatomical shapes to accommodate patient anatomy.

KONG®-C VBR System

The KONG®-C VBR System is a vertebral body replacement system for anterior stabilization of the cervical spine. This device serves as a replacement for vertebral bodies in tumorous and traumatic diseases which lead to instabilities in the anterior support or compression of neural structures or diseases that make an infection repair necessary. The KONG®-C VBR System is a modular design with various heights, widths, and angles. The system consists of a lordotic body structure that ranges in height from 5 – 55mm with a width and depth of 13mm, and surface treads on its cranial and caudal end plate surfaces that serve to guide and anchor the implant. The overall height of the VBR device including body and end plates ranges from 16 to 66 mm. The end plates

have a geometry that range from 0 to 6° and are manufactured in the following sizes: 14 x 13mm, 16 x 13mm, and 18 x 14mm. The tread surfaces help to improve primary fixation stability of the end plates. The large contact surface of the end plates reduces the risk of migration. The screw to secure the end plates to the body has a length of 7 mm and a thread size of M6.

The KONG®-C VBR System is composed of BlackArmor® material, a carbon fiber reinforced polyetheretherketone (Carbon/PEEK) composite. Due to the excellent biocompatibility and material properties, Carbon/PEEK has been in clinical use in spine surgery for more than 20 years world-wide. The BlackArmor® material is a combination of continuous, high strength carbon fiber-reinforced PEEK and icotec's composite flow molding (CFM) process. The result is a non-metallic implant component with an interwoven 3D fiber architecture that provides strength and endurance. BlackArmor® is radiolucent in all diagnostic imaging modes (MRI, CT and X-ray) and will therefore not create imaging artifacts. Embedded tantalum markers (per ASTM F560) ensure the required radiologic visibility of the implant during surgery and follow-up. The KONG®-C VBR System incorporates a rough cp-titanium coating (per ASTM F1580), designed to improve direct bone apposition.

The implants are supplied sterile and are available in a variety of heights, footprints and anatomical shapes to accommodate patient anatomy.

Predicate Device:
icotec ag submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, KONG®-TL VBR System and KONG®-C VBR System are substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: KONG®-TL VBR System and KONG®-C VBR System (K200235)
Reference Device: icotec VADER Pedicle System (K222789)

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

Additionally, non-clinical performance testing was performed in accordance with the FDA Guidance Document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" to support labeling the subject device as MR Conditional.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate device (K200235) 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.

The updated manufacturing does not raise new issues or concerns of safety or efficacy.

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 similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The KONG®-TL VBR System and KONG®-C VBR System are as safe, as effective, and performs as well as, or better, than the predicate devices.