May 29, 2020

icotec ag
% Mr. Samuel Pollard
Associate Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K200235
Trade/Device Name: KONG-TL® VBR System, 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: May 7, 2020
Received: May 7, 2020

Dear Mr. 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. 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 Showalter, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200235

Device Name

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

Indications for Use *(Describe)*

Cervical

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.

Thoracolumbar

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.

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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K200235 - 510(k) Summary

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

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Date Prepared: January 30, 2020

Classification: 21 CFR §888.3060, Spinal intervertebral body fixation orthosis
Class: II

Product Code: MQP, PLR

Primary Predicates: Omnia Medical VBR (K191778),

Additional Predicates: NuVasive Monolith Cervical Corpectomy System (K180550), Ulrich Small VBR (K192117), Solidity™ Vertebral Body Replacement (K181921), CAPRI Corpectomy Cage System (K180665), Obelisc Vertebral Body Replacement Device (K060416), Synthes CRL System (K103320)

Reference Devices: icotec VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (K190545), icotec Interbody Cage System (K172480)

Indications for Use:

Cervical

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. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.

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.

Thoracolumbar

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.

Device Description:
The KONG®-TL VBR System and the KONG®-C VBR System are vertebral body replacement systems designed to improve the stability of the cervical and thoracolumbar spine. The devices are manufactured from high strength carbon fiber reinforced polyetheretherketone (Carbon/PEEK, BlackArmor®) and incorporate a rough titanium coating (Ti-iT®). The devices are intended to be used with supplemental spinal fixation.

Each implant is provided sterile and is available in an assortment of heights, footprints, and lordosis angles to accommodate patient anatomy.

Primary Predicate Devices:
The KONG®-TL VBR System and the KONG®-C VBR System is substantially equivalent to the Omnia Medical VBR (K191778).

Additional Predicate Devices:

- NuVasive Monolith Cervical Corpectomy System (K180550)
- Ulrich Small VBR (K192117)
- Solidity™ Vertebral Body Replacement (K181921)
- CAPRI Corpectomy Cage System (K180665)
- Obelisc Vertebral Body Replacement Device (K060416)
- Synthes XRL System (K103320)

Reference Devices:
The following devices are used as reference devices throughout this submission:

- icotec VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (K190545),
- icotec Interbody Cage System (K172480)

Performance Testing Summary:
The non-clinical tests performed by the company include static and dynamic compression, 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 KONG®-C VBR System and the KONG®-TL VBR System are substantially equivalent to legally marketed predicate devices.

Technological Characteristics:
the KONG®-C VBR System and the KONG®-TL VBR System possesses the same technological characteristics as one or more of the predicate devices. These characteristics include, the basic design (expanding corpectomy spacer), the carbon fiber reinforced polyetheretherketone (Carbon/PEEK, BlackArmor®) and a rough titanium coating (Ti-iT®), the endplate sizes (dimensions are comparable to those offered by predicate systems), the spiked design (the spiked feature is seen among multiple VBR system endplates) and the fundamental scientific technology.

Substantial Equivalence:
The subject devices were demonstrated to be substantially equivalent to predicates cited in the above with respect to indications, design, materials, function, manufacturing, and performance. The non-clinical tests performed by the include static and dynamic compression, 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 KONG®-C VBR System and the KONG®-TL VBR 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 KONG®-TL VBR System and the KONG®-C VBR System to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate devices.