ulrich GmbH & Co. KG
℅ Mr. Hans Stover
President & CEO
ulrich medical USA
18221 Edison Avenue
Chesterfield, Missouri 63005

November 1, 2019

Re: K192117
Trade/Device Name: Small VBR™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: August 5, 2019
Received: August 6, 2019

Dear Mr. Stover:

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
Ronald P. Jean, Ph.D.
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)*

K192117

Device Name
Small VBR™

Indications for Use *(Describe)*

The Small VBR is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Small VBR is also 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Small VBR is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Small VBR is optional.

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

Date:	5 August 2019
Sponsor:	ulrich GmbH & Co. KG Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0) 731-9654-1304 Fax: +49 (0) 731-9654-2802
Contact Person:	Hans Stover ulrich medical USA, Inc. 18221 Edison Avenue Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Proposed Trade Name:	Small VBR™
Common Name:	Vertebral body replacement
Device Classification:	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation:	21 CFR 888.3060
Device Product Code:	MQP, PLR
Purpose:	The aim of this submission is to request additional cervical spine indications for the Small VBR™.
Device Description:	Small VBR™ is a system of corpectomy devices used to provide mechanical support to the cervical and thoracolumbar spine. Small VBR™ is a cylindrical implant with the capability for device expansion. The ends of the device incorporate a ring of teeth to engage the endplates of adjacent vertebrae. The device is offered non-sterile in various combinations of expansion range, angulation and footprint to accommodate patient anatomy.
Intended Use:	The Small VBR is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders. The Small VBR is also 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The Small VBR is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Small VBR is optional.
Materials:	Small VBR™ implants are manufactured from Ti-6Al-4V ELI titanium alloy (per ASTM F136).

Primary Predicate:	Fortify® (Globus Medical Inc. – K173982)
Additional Predicates:	VBR™ (Osteotech Inc. – K012254), Rezaian Spinal Fixator (Orthopedic Equipment Co. Inc. – K841189)
Performance Data:	Mechanical testing of the worst case Small VBR™ devices included static and dynamic compression and static and dynamic torsion following ASTM F2077. The mechanical test results demonstrate that Small VBR™ device performance is substantially equivalent to itself as a predicate device.
Technological Characteristics:	The Small VBR™ possesses the same technological characteristics as one or more of the predicate devices. These include: • basic design (expanding corpectomy spacer), • material (titanium alloy), • sizes (dimensions are comparable to those offered by the predicate systems) and The fundamental scientific technology of the Small VBR™ is the same as previously cleared devices.
Conclusion:	The Small VBR™ possesses the same intended use and technological characteristics as the predicate devices. Therefore Small VBR™ is substantially equivalent for its intended use.