Zavation Medical Products LLC
Frankie Cummins
Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

August 6, 2019

Re: K191423
Trade/Device Name: Normandy VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: July 17, 2019
Received: August 1, 2019

Dear Mr. Cummins:

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 Melissa Hall
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)*
K191423

Device Name

Normandy VBR System

Indications for Use *(Describe)*

The Normandy VBR System is indicated for use in the cervical spine (C2-C7), and thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, 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 Normandy VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Normandy VBR System 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 Normandy VBR System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, and anterior plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

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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510K Summary

Date:	Aug 2, 2019
Submitter:	Zavation Medical Products LLC 220 Lakeland Parkway Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Frankie Cummins
Trade name:	Normandy VBR System
Classification:	Regulation Number: 21 CFR 888.3060 Regulation Name: Spinal Intervertebral Body Fixation Orthosis Regulatory Class: Class II Product Code: MQP, PLR
Predicates:	Primary: K180673 Zavation Normandy VBR System Additional: K060416 Ulrich Medical Obelisc K142205 Nuvasive X-Core
Purpose:	The purpose of this submission is to add new thoracolumbar sizes to the Normandy VBR system

Device Description:

The Normandy VBR System is an adjustable height vertebral body replacement device that is implanted into the vertebral body space to provide structural stability in skeletally mature patients following corpectomy or vertebrectomy. The system is comprised of spacers of various sizes and options to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. The device is mechanically locked at the required height by means of a locking screw. Each spacer has an axial hole to allow autograft or allograft to be packed inside each spacer. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Components are manufactured from titanium alloy (Ti-6AL-4V) per ASTM F-136.

Intended Use:
The Normandy VBR System is indicated for use in the cervical spine (C2-C7) and thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, 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 Normandy VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Normandy VBR System 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 Normandy VBR System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, and anterior plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Technological Characteristics:
The Normandy VBR System implants have the same technological characteristics as the predicate devices including, design, intended use, material composition, function, and range of sizes.

Performance Data:
Mechanical test results demonstrated that the Normandy VBR System is substantially equivalent to the predicate devices. The following non-clinical tests were conducted: Static and Dynamic Axial Compression, Static and Dynamic Torsion per ASTM F2077, Subsidence per ASTM F2267, and Expulsion testing.

Conclusion:
The Normandy VBR System is substantially equivalent to the predicate device referenced above.