Omnia Medical, LLC
% Kevin Majka
Quality System/Regulatory Engineer
JALEX Medical
30311 Clemens Road
Suite 5D
Westlake, Ohio 44145

October 26, 2017

Re: K172323
Trade/Device Name: Omnia Medical VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 28, 2017
Received: August 1, 2017

Dear Mr. Majka:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K172323

Device Name
Omnia Medical VBR

Indications for Use *(Describe)*

The Omnia Medical VBR is a vertebral body replacement system indicated for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The device is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitted By:	Omnia Medical, LLC 1000 Hampton Center Suite G Morgantown, WV 26505
Date:	07/28/2017
Contact Person:	Kevin Majka, Quality System/Regulatory Engineer
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Device Trade Name:	Omnia Medical VBR
Device Classification Name:	Spinal intervertebral body fixation orthosis (21 CFR 888.3060)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	MQP
Primary Predicate Device:	Vu Mesh VBR (K070381) The predicate device has never been subject to a recall.
Reference Devices:	Arena-C® HA PEEK Cervical Intervertebral Body Fusion Device (K142026) Talos®-C (HA) Cervical Intervertebral Body Fusion Devices (K142345)

Device Description:

The Omnia Medical VBR is manufactured from PEEK-OPTIMA™ HA Enhanced conforming to ASTM F2026 and tantalum markers conforming to ASTM F560. This implant is available in two footprint sizes and offers spacers and endplates which allow for fine adjustments of the height and lordosis to accommodate various patient anatomy. The device features a hollow center and through holes for use with autograft or allograft to encourage formation of new bone. The device is intended to be used with supplemental fixation.

Indications for Use:

The Omnia Medical VBR is a vertebral body replacement system indicated for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The device is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

Summary of Technological Characteristics:

The Omnia Medical VBR and the predicate have the same intended use and fundamental scientific technology. Both devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static and dynamic compression per ASTM F2077, static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267, and expulsion testing.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.