Omnia Medical, LLC
% Daniel Johnson
Regulatory Engineer
JALEX Medical
30311 Clemens Rd Suite 5D
Westlake, Ohio 44145

August 28, 2019

Re: K191778
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: PLR, MQP
Dated: August 7, 2019
Received: August 8, 2019

Dear Daniel Johnson:

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)*

K191778

Device Name
Omnia Medical VBR

Indications for Use *(Describe)*

The Omnia Medical VBR is a vertebral body replacement system indicated for use in skeletally mature patients to replace a collapsed, damaged, diseased, or unstable vertebral body due to tumor or trauma (i.e. fracture) or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The device is intended for use in the cervical spine (from C3 to C7) and in the thoracolumbar spine (from T1-L5). The device is intended for use with supplemental fixation cleared by the FDA for use in the cervical, thoracic, or lumbar spine and is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

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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"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
6 Canyon Road Suite 300
Morgantown, WV 26508

Date: 8/27/19

Contact Person: Daniel Johnson, 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: PLR, MQP
Primary Predicate Device: NuVasive® Monolith™ Cervical Corpectomy System (K180550)
The predicate device has never been subject to a recall.
Additional Predicate Device: Omnia Medical VBR (K172323)
The additional predicate device has never been subject to a recall.

Device Description:

The Omnia Medical VBR is manufactured from PEEK-OPTIMA™ HA Enhanced 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 in skeletally mature patients to replace a collapsed, damaged, diseased, or unstable vertebral body due to tumor or trauma (i.e. fracture) or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The device is intended for use in the cervical spine (from C3 to C7) and in the thoracolumbar spine (from T1-L5). The device is intended for use with supplemental fixation cleared by the FDA for use in the cervical, thoracic, or lumbar spine and is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Summary of Technological Characteristics:

The Omnia Medical VBR and the predicates have the same intended use and fundamental scientific technology. The Omnia Medical VBR and the predicates demonstrate substantial equivalence based on the following characteristics:

- Design features and function
- Device components
- Footprint sizes

- Cage heights
- Endplate angles
- Graft openings
- Insertion features
- Materials

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. This data was presented in the reference predicate submission (K172323) to demonstrate substantial equivalence. No new device designs or worst-case sizes are being introduced. The previously submitted data supports the expanded indications for use.

Conclusion:

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