



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

February 6, 2018

Re: K183659
Trade/Device Name: Omnia Medical Rotary PLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 26, 2018
Received: December 27, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183659

Device Name

Omnia Medical Rotary PLIF System

Indications for Use (Describe)

The Omnia Medical Rotary PLIF System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. The Omnia Medical Rotary PLIF System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

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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510(k) Summary

Submitted By: Omnia Medical, LLC
6 Canyon Rd Suite 300
Morgantown, WV 26508

Date: 12/26/2018

Contact Person: Daniel Johnson
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Omnia Medical Rotary PLIF System
Device Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: MAX
Primary Predicate Device: Atlas Spine Spacer (K091406)
The predicate device has never been subject to a recall
Reference Device: Atlas Spine Vertebral Body Replacement (K063205)

Device Description:

The Omnia Medical Rotary PLIF is manufactured from PEEK-OTIMA™ LT1 conforming to ASTM F2026 and tantalum markers conforming to ASTM F560. The Omnia Rotary PLIF is rectangular in shape and available in various sizes with heights ranging from 9mm to 17mm and 0° or 7° of lordosis. The leading end is tapered or bulleted for ease of insertion. All devices are 25mm in length. The device has six tantalum markers for radiographic confirmation of device position and orientation. The device is intended to be used with supplemental fixation.

Indications for Use:

The Omnia Medical Rotary PLIF System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. The Omnia Medical Rotary PLIF System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

Summary of Technological Characteristics:

The Omnia Medical Stature Spacer 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:

Engineering rationales were provided to leverage the mechanical testing of the predicates for this submission. Mechanical testing on the predicate included static and dynamic compression per ASTM F2077, static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267, and expulsion testing. These rationales and performance tests support substantial equivalence.

Conclusion:

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