December 23, 2020

Omnia Medical, LLC
℅ Jordan Floyd
Project Engineer
JALEX Medical
27865 Clemens Rd, Suite 3
Westlake, Ohio 44145

Re: K203207
Trade/Device Name: Omnia Medical TiBrid™-SA
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: October 14, 2020
Received: October 30, 2020

Dear Jordan Floyd:

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,

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203207

Device Name
Omnia Medical TiBrid™-SA

Indications for Use *(Describe)*
The TiBrid™-SA system is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should have six months of nonoperative therapy. This device is intended for use with autogenous bone graft and/or allograft compromised of cancellous and/or corticocancellous bone graft and integrated fixation.

The TiBrid™-SA is a standalone device and must be used with the internal bone screws provided.

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 Road Suite 300
Morgantown, WV 26508

Date: 10/14/2020

Contact Person: Jordan Floyd, Project Engineer
Contact Telephone: (440) 396-4041
Contact Fax: (440) 933-7839

Device Trade Name: Omnia Medical TiBrid™-SA

Common Name: Intervertebral Body Fusion Device
Device Classification Name: Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: OVD

Primary Predicate Device: Globus Medical Independence MIS® Spacer (K170157)

Additional Predicates: Omnia TiBrid™-A Intervertebral Fusion Device (K190363)

Device Description:

The Omnia Medical TiBrid™-SA System is a standalone intervertebral body fusion system used in the spine to replace a collapsed, damaged, or unstable disc. The implantable devices are manufactured from PEEK-OPTIMA™ HA Enhanced, titanium alloy, and tantalum for radiographic visualization. Each device is available in multiple footprints, heights, and angles. The implants feature a hollow center to accommodate autograft or allograft and include anti-migration features. All devices are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and integrated fixation.

Indications for Use:

The TiBrid™-SA system is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should have six months of nonoperative therapy. This device is intended for use with autogenous bone graft and/or allograft compromised of cancellous and/or corticocancellous bone graft and integrated fixation.

The TiBrid™-SA is a standalone device and must be used with the internal bone screws provided.

Summary of Technological Characteristics:

The Omnia Medical TiBrid™-SA System and the predicates have the same intended use and fundamental scientific technology. All 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, static and dynamic compression shear 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.