April 24, 2024

Omnia Medical, LLC
℅ Jennifer Palinchik
President
JALEX Medical, LLC
27865 Clemens Rd., Suite 3
Westlake, Ohio 44145

Re: K240623
Trade/Device Name: Omnia Medical TiBrid™-SA System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 20, 2024
Received: March 20, 2024

Dear Jennifer Palinchik:

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 (the 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 available 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240623

Device Name

Omnia Medical TiBrid™-SA System

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 or TiBrid™-SA plate and 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: 04/15/2024

Contact Person: Jennifer Palinchik, President, JALEX Medical
Contact Telephone: (440) 935-3282
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: Omnia TiBrid™-SA Intervertebral Fusion Device (K203207)
Additional Predicate: SeaSpine Zuma™ System (K082926)

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 or TiBrid™-SA plate and bone screws provided.

Summary of Technological Characteristics:

The Omnia Medical TiBrid™-SA System and the predicate devices have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features

- Intended use
- Materials
- Dimensions
- Function

Item	Subject Device: Omnia Medical TiBrid™-SA	Omnia Medical TiBrid™-SA (K203207)	Zuma™ System, SeaSpine Inc. (K082926)	Comparison
Comparison component to subject device	N/A	Interbody, screws, screw covers	Interbody, screws, and plate combination	N/A
Device Classification Name	Intervertebral Fusion Device with Integrated Fixation, Lumbar	Intervertebral Fusion Device with Integrated Fixation, Lumbar	Intervertebral Fusion Device with Integrated Fixation, Lumbar	Equivalent
Regulation	21 CFR 888.3080	21 CFR 888.3080	21 CFR 888.3080	Equivalent
Common Name	Intervertebral Body Fusion Device	Intervertebral Body Fusion Device	Intervertebral Body Fusion Device	Equivalent
Product Code	OVD	OVD	OVD	Equivalent
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	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	When used as an intervertebral body fusion device, the Zuma-L System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous	Equivalent

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	may be packed with autogenous bone graft material. The TiBrid™-SA is a standalone device and must be used with the internal bone screws or TiBrid™-SA plate and bone screws provided.	may be packed with autogenous bone graft material. The TiBrid™-SA is a standalone device and must be used with the internal bone screws provided.	non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autograft. Zuma-L is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. When used as a Vertebral Body Replacement Device, the Zuma-L System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Zuma-L System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for	

			a prolonged period. Additionally, Zuma-L is intended for use with bone graft.	
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 and heights. 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.	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 and heights. 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.	Zuma is an implantable spinal device made from PEEK-OPTIMA® LT1 and titanium with tantalum markers for radiographic visualization. It is secured to vertebral bodies with titanium bone screws. The device has open central area for receiving bone graft material and is offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy.	Equivalent
Footprint Sizes (width x length)	32mm x 25mm	32mm x 25mm	26mm x 24mm	Equivalent
	36mm x 27mm	36mm x 27mm	32mm x 25mm	
	40mm x 29mm	40mm x 29mm	38mm x 26mm	
Interbody Heights	10, 12, 14, 16, 18mm	10, 12, 14, 16, 18mm	10, 12, 14, 16, 18mm	Equivalent
Interbody Angles	8, 12, 16, 20°	8, 12, 16, 20°	8, 12°	Equivalent

Graft Window	Yes	Yes	Yes	Equivalent
Insertion Feature	Threaded hole	Threaded hole	Threaded hole	Equivalent
Anti-Migration Features	Yes	Yes	Yes	Equivalent
Use with supplemental fixation	No	No	Fusion device - no Body replacement - yes	Equivalent
Interbody Material & Manufacturing	PEEK-OPTIMA™ HA Enhanced (per ASTM F2026), Ti-6Al-4V ELI (per ASTM F3001), Tantalum (per ASTM F560).	PEEK-OPTIMA™ HA Enhanced (per ASTM F2026), Ti-6Al-4V ELI (per ASTM F3001), Tantalum (per ASTM F560).	PEEK-OPTIMA® LT1, Titanium alloy, Tantalum marker	Equivalent
Screw Diameters	5.5mm, 6.0mm self tapping and self drilling	5.5mm, 6.0mm self tapping and self drilling	5.5mm, 6mm self-tapping	Equivalent
Screw Lengths	15 - 35mm (5mm increments)	15 - 35mm (5mm increments)	20, 25, 30, 35mm	Equivalent
Screw Material	Medical grade Ti6Al4V ELI per ASTM F136	Medical grade Ti6Al4V ELI per ASTM F136	Medical grade Ti6Al4V ELI	Equivalent
Plate Lengths	30, 32, 34, 36, 38 mm	N/A	43, 44, 45 mm	Equivalent

Performance Data – Non-Clinical:

Non-clinical tests were conducted to verify that the proposed device met all design specifications as Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with ASTM F2077 Standard Test Methods for Intervertebral Body Fusion Devices by performing static and dynamic compression shear testing.

Performance Data – Clinical:

Clinical Studies were not applicable to support a substantial equivalence determination for this device. The mechanical testing results, material, indications and intended uses, and device function are comparable to the predicate device.

Conclusion:

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