November 15, 2022

Omnia Medical, LLC
Daniel Johnson
Project Engineer
6 Canyon Road, Suite 300
Morgantown, West Virginia 26508

Re: K212612
Trade/Device Name: Omnia Medical TiBrid™-SC
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 14, 2022
Received: October 17, 2022

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,

Brent Showalter -S

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)*
K212612

Device Name
Omnia Medical TiBrid™-SC

Indications for Use *(Describe)*
The TiBrid™-SC standalone cervical intervertebral fusion device is indicated for use in anterior cervical interbody procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. The implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The device is to be used is patients who have had six weeks of non-operative treatment. The cervical standalone intervertebral body fusion device is to be used with either two bone screws and a screw locking cover or a connecting plate. If the connecting plate is chosen, the number of screws should correspond to the number of holes in the plate.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: 08/16/2021

Contact Person: Daniel Johnson, Project Engineer
Contact Telephone: (440) 333-2127
Contact Fax: (440) 933-7839

Device Trade Name: Omnia Medical TiBrid™-SC
Common Name: Intervertebral Body Fusion Device
Device Classification Name: Intervertebral Body Fusion Device with Integrated Fixation, Cervical

Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: OVE

Primary Predicate Device: SeaSpine® Shoreline™ ACS – Anterior Cervical Standalone System (K170569)
The primary predicate device has never been subject to a recall.

Reference Devices: Omnia Medical TiBrid™ Cervical Cage (K190363)
Omnia Medical TiBrid™-SA (K203207)
NuVasive CoRoent Small Interlock System (K192582)
The reference predicate device has never been subject to a recall.

Device Description:
The TiBrid™-SC system consists of a standalone hybrid PEEK OPTIMA™ HA Enhanced and titanium alloy cervical interbody device with 3 titanium plate options (two, three, and four screws) that can be connected to the standalone device. The standalone cages are available in multiple footprints and heights, and have a lordotic angle of 6°. The plates are available in multiple heights. The cages 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.

Indications for Use:
The TiBrid™-SC standalone cervical intervertebral fusion device is indicated for use in anterior cervical interbody procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. The implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The device is to be used is patients who have had six weeks of non-operative treatment. The cervical standalone intervertebral body fusion device is to be used with either two bone screws and a screw locking cover or a connecting plate. If the connecting plate is chosen, the number of screws should correspond to the number of holes in the plate.

Summary of Technological Characteristics:
The Omnia Medical TiBrid™-SC System and the primary predicate have the same intended use and fundamental scientific technology. All devices compare similarly in:

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

Table 8.1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems

	Table 8.1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems				
Item	**Omnia Medical TiBrid™-SC**	**SeaSpine Shoreline™ ACS - Anterior Cervical Standalone System (K170569)**	**Omnia Medical TiBrid™-C (K190363)**	**NuVasive CoRoent Small Interlock System (K192582)**	**Comparison**
Classification Name	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Intervertebral Fusion Device with Bone Graft, Cervical	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Equivalent
Regulation	21 CFR 888.3080	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	Intervertebral Body Fusion Device	Equivalent
Product Code	OVE	OVE	ODP	OVE	Equivalent
Indications for Use	The TiBrid™-SC standalone cervical intervertebral fusion device is indicated for use in anterior cervical interbody procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. The implants are to be used with autogenous bone graft and/or	The SeaSpine Shoreline™ ACS is a standalone device indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease of the cervical spine at a single level (C2-T1). The Shoreline™ ACS implants are to be used with autograft bone graft and/or allogenic bone graft composed of	The TiBrid™ Cervical Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels within the cervical spine at disc levels from C2 to T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic	The CoRoent Small Interlock System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple	

Omnia Medical

	Table 8.1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems				
Item	**Omnia Medical TiBrid™-SC**	**SeaSpine Shoreline™ ACS - Anterior Cervical Standalone System (K170569)**	**Omnia Medical TiBrid™-C (K190363)**	**NuVasive CoRoent Small Interlock System (K192582)**	**Comparison**
	allograft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The device is to be used is patients who have had six weeks of non-operative treatment. The cervical standalone intervertebral body fusion device is to be used with either a minimum of two bone screws and a screw locking cover or a connecting plate.	cancellous and/or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The cervical device is to be used with Shoreline bone screw fixation and the Shoreline locking cover.	studies. Patients should have had at least six weeks of non-operative treatment prior to treatment with intervertebral cages. This device is intended for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation.	contiguous levels from C2-T1. The System is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion.	
Description	The TiBrid™-SC system consists of a standalone hybrid PEEK OPTIMA™ HA Enhanced and titanium alloy cervical interbody device with 3 titanium plate options (two, three, and four screws) that can be connected to the standalone device. The standalone cages are available in multiple footprints and	The SeaSpine® Shoreline™ ACS - Anterior Cervical Standalone System consists of the implant assembly composed of a single use PEEK cervical spacer (ASTM F2026) and a titanium alloy (ASTM F136) plate with titanium alloy variable angle or fixed bone screws, and a titanium alloy locking cover. Shoreline™ ACS is offered in a variety of footprints and	The Omnia Medical TiBrid™ Systems are intervertebral body fusion systems 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 implant features a	The NuVasive CoRoent Small Interlock System is a standalone anterior cervical interbody device consisting of a PEEK (polyetheretherketone) implant cage with titanium alloy and tantalum radiographic markers, titanium alloy washers, and three (3) titanium alloy bone fixation screws. The devices are manufactured from PEEK-Optima® LT1 conforming to ASTM F2026,	Equivalent

Omnia Medical

	Table 8.1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems				
Item	**Omnia Medical TiBrid™-SC**	**SeaSpine Shoreline™ ACS - Anterior Cervical Standalone System (K170569)**	**Omnia Medical TiBrid™-C (K190363)**	**NuVasive CoRoent Small Interlock System (K192582)**	**Comparison**
	heights, and have a lordotic angle of 6°. The plates are available in multiple heights. The cages 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.	heights to accommodate variations in patient anatomy and is generally box-shaped with surface teeth and a central canal for receiving autograft bone graft material and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The system is implanted via an anterior approach.	hollow center to accommodate autograft or allograft and includes 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 supplemental fixation.	titanium alloy conforming to ASTM F136, and tantalum conforming to ASTM F560. The implants are available in a variety of sizes to accommodate anatomical conditions. The CoRoent Small Interlock System is a standalone system intended to be used with the bone screws provided, and when used as such requires no additional supplemental fixation.	
Interbody Footprints	16.5 x 14.5mm 18 x 15mm	16 x 14mm 18 x 15mm 20 x 15mm	14mm x 12mm 16mm x 13.5mm 18mm x 15mm	17mm x 14mm	Equivalent
Interbody Heights	6 - 12 mm, 1 mm increments	5 - 12 mm, 1 mm increments	5 - 12 mm, 1 mm increments	5 - 12 mm, 1 mm increments	Equivalent
Interbody Lordosis	6°	7°, 10°, 15°	6°	6°	Equivalent
Plate Configurations	2,3 and 4 screw	2,3, and 4 screw	N/A	N/A	Equivalent
Screw Diameters	Ø4.0 or 4.5 mm	Ø3.5 or 4.0 mm	N/A	Ø4.0 or 4.5 mm	Equivalent
Screw Lengths	10 – 18 mm	10 - 18mm	N/A	12 – 16 mm	Equivalent
Screw Styles	Self-Drilling & Self-Tapping, Fixed & Variable	Self-Drilling & Self-Tapping, Fixed & Variable	N/A	Self-Drilling & Self-Tapping, Fixed & Variable	Equivalent
Graft Windows	Yes	Yes	Yes	Yes	Equivalent
Bone Graft Contact Area	73 mm^2	65 mm^2	63 mm^2	Unknown	Equivalent
Insertion Features	Threaded hole	Threaded hole	Threaded hole	Unknown	Equivalent

	Table 8.1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems				
Item	**Omnia Medical TiBrid™-SC**	**SeaSpine Shoreline™ ACS - Anterior Cervical Standalone System (K170569)**	**Omnia Medical TiBrid™-C (K190363)**	**NuVasive CoRoent Small Interlock System (K192582)**	**Comparison**
Anti-Migration Features	Yes	Yes	Yes	Yes	Equivalent
Interbody Materials	PEEK-OPTIMA™ HA Enhanced per ASTM F2026, Titanium Alloy per ASTM F3001, Titanium Alloy per ASTM F136	PEEK-OPTIMA™ per (ASTM 2026), titanium alloy (ASTM F136), Tantalum (ASTM f560), CP Titanium Surface (ASTMf67)	PEEK-OPTIMA™ HA Enhanced (per ASTM F2026) and Ti-6Al-4V ELI (per ASTM F3001), Titanium Alloy per ASTM F136	PEEK-OPTIMA™ per (ASTM 2026), titanium alloy (ASTM F136)	Equivalent
Plate Materials	Titanium Alloy per ASTM F136	Titanium Alloy per ASTM F136	N/A	N/A	Equivalent
Screw Materials	Titanium Alloy per ASTM F136	Titanium Alloy per ASTM F136	N/A	Titanium Alloy per ASTM F136	Equivalent

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 (i.e. design, material, and chemical composition), and comparison with the predicate device, the subject device has demonstrated substantial equivalence.