March 13, 2023

Omnia Medical, LLC
% Jennifer Palinchik
President
Jalex Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K223321
Trade/Device Name: Omnia Medical Coupler-C Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 17, 2023
Received: January 19, 2023

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 (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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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)*
K223321

Device Name
Omnia Medical Coupler-C Anterior Cervical Plate

Indications for Use *(Describe)*
The Omnia Medical Coupler-C Anterior Cervical Plate is indicated for use in temporarily stabilizing the anterior spine from C2 to T1 during the development of cervical spinal fusion in patients with degenerative disc disease (DDD, neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumors, pseudoarthrosis, or failed previous fusion.

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:	01/17/2023
Contact Person:	Jennifer Palinchik, President
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Device Trade Name:	Omnia Medical Coupler-C Anterior Cervical Plate
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Device Classification Name:	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	KWQ
Primary Predicate Device:	K143626- Zimmer Spine Invizia Anterior Cervical Plate System The primary predicate device has never been subject to a recall.
Additional Predicates:	K113329 K2M Pyrenees Cervical Plate System K183056 Globus ASSURE Anterior Cervical Plate System K182489 Solco 4CIS® Pinehurst Anterior Cervical Plate System

Device Description:

The Omnia Medical Coupler-C Anterior Cervical Plate system includes plates, screws, and an instrument set used to insert the implants. The implants are composed of Ti-6Al-4V ELI per ASTM F136. The screws are inserted into the vertebral body through corresponding holes in the plate to achieve fixation. A screw locking system is incorporated in the plate, allowing the surgeon to lock screws into place with anti-backout mechanisms after insertion. The plates are available in multiple lengths and levels to allow for utilization in fusion operations across 1 to 4 levels of the cervical spine. The system instrumentation is manufactured from surgical grade stainless steel (17-4 PH per ASTM F899) and other surgical grade materials. The instrumentation is used to prepare the site and to implant the device.

Indications for Use:

The Omnia Medical Coupler-C Anterior Cervical Plate is indicated for use in temporarily stabilizing the anterior spine from C2 to T1 during the development of cervical spinal fusion in patients with degenerative disc disease (DDD, neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumors, pseudoarthrosis, or failed previous fusion.

Summary of Technological Characteristics:

The Omnia Medical Coupler-C Anterior Cervical Plate and the predicate have the same intended use and fundamental scientific technology. All devices compare similarly in:

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

Table 1: Dimensions and Technological Characteristics Comparison Cervical Plate Systems

Item	Omnia Coupler Cervical Plate	Zimmer InViZia Cervical Plate (K143626)	Comparison
Classification Name	Spinal Intervertebral Body Fixation Orthosis	Spinal Intervertebral Body Fixation Orthosis	Equivalent
Regulation	21 CFR 888.3060	21 CFR 888.3060	Equivalent
Product Code	KWQ	KWQ	Equivalent
Indications for Use	The Omnia Medical Coupler-C Anterior Cervical Plate is in indicated for use in temporarily stabilizing the anterior spine from C2 to T1 during the development of cervical spinal fusion in patients with degenerative disc disease (DDD, neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumors, pseudoarthrosis, or failed previous fusion.	The inViZia® Anterior Cervical Plate System is designed for anterior interbody screw fixation of the cervical spine at levels C2-T1. The inViZia® Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.	Equivalent
Description	The Omnia Medical Coupler-C Anterior Cervical Plate system includes plates and screws, and an instrument set used	The Zimmer Spine Anterior Cervical and	Equivalent

	in the surgical insertion of the implants. The implants are composed of Ti-6Al-4V ELI per ASTM F136. The screws are inserted into the vertebral body through corresponding holes in the plate in order to achieve fixation. A screw locking system is incorporated in the plate, allowing the surgeon to lock screws into place with anti-backout mechanisms after insertion. The plates are available in multiple lengths and levels to allow for utilization in fusion operations across 1 to 4 levels of the cervical spine. The system instrumentation is manufactured from surgical grade stainless steel (17-4 PH per ASTM F899) and other surgical grade materials. The instrumentation is used to prepare the site and in placement of the device.	Lumbar Plate Systems are intended to provide stabilization of the spine during the development of a solid spinal fusion in patients per the system(s) indications at various spinal levels. The Zimmer Spine Anterior Cervical and Lumbar Plate Systems consist of plates, bone screws and instruments necessary to implant the specific system. Bone screws are secured to the plate through locking caps and/or a Secure Ring® mechanism. The plates are available in various sizes and lengths and the bone screws are available in various diameters and lengths.	
Plate Sizes	1 Level: 21-33mm, 2mm increments 2 Level: 33-55mm, 2mm increments 3 Level: 51-78mm, 3mm increments 4 Level: 73-105mm, 4mm increments	1 Level: 18-34mm, 2mm increments 2 Level: 34-54mm, 2mm increments 3 Level: 48-72mm, 3 mm increments 4 Level: 68-92mm, 4mm increments	Equivalent
Plate length (hole-to-hole)	1 Level: 12-24mm, 2mm increments 2 Level: 24-36mm, 2mm and 3mm increments 3 Level: 42-69mm, 3mm increments 4 Level: 64-96mm, 4mm increments	NA	Equivalent
Plate Thickness	2mm	<2mm	Equivalent
Screw Sizes	Diameters: 4.0 and 4.5mm Lengths: 8-18mm, 2mm increments	Diameters: 4.2 and 4.6 mm Lengths: 12-16mm, 2mm increments	Equivalent
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Equivalent

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing, including static and dynamic compression bending, and static torsion per ASTM F1717. Results support that the subject device has demonstrated substantial equivalence.

Conclusion:

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