April 12, 2023

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

Re: K230424
Trade/Device Name: Omnia Medical Coupler-A™ Anterior Lumbar Plate System; Omnia Medical Coupler-L™ Lateral Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 15, 2023
Received: February 17, 2023

Dear Ms. 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)*
K230424

Device Name
Omnia Medical Coupler-A™ Anterior Lumbar Plate System and Omnia Medical Coupler-L™ Lateral Lumbar Plate System

Indications for Use *(Describe)*
The Coupler-A™ and Coupler-L™ Lumbar Plate Systems are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the vessels or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation)
- Deformities (i.e. Scoliosis, Kyphosis or Lordosis)
- 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:	02/16/2023
Contact Person:	Jennifer Palinchik, President, JALEX Medical
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Contact Address:	JALEX Medical, LLC 27865 Clemens Rd Suite 3 Westlake, Ohio 44145
Device Trade Name:	Omnia Medical Coupler-A™ Anterior Lumbar Plate System and Omnia Medical Coupler-L™ Lateral Lumbar Plate System
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:	K221728 Stryker LITe® Plate System The primary predicate device has never been subject to a recall.

Device Description:
The Coupler-A™ and Coupler-L™ Lumbar Plate Systems provide stabilization to the lumbar spine during spinal fusion. These systems include plates, screws, and an instrument set used in the surgical insertion of the implants. The implants are composed of Ti6Al4V ELI Titanium 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 the screws into place with cam screws after insertion. The plates are available in multiple lengths to allow for utilization in fusion operations across L1 to S1 of the lumbar spine. The system instrumentation is manufactured from surgical grade stainless steel and other surgical grade materials. The instrumentation is used in the placement and fixing of the device.

Indications for Use:
The Coupler-A™ and Coupler-L™ Lumbar Plate Systems are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the vessels or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation)

- Deformities (i.e. Scoliosis, Kyphosis or Lordosis)
- Failed Previous Fusion

Summary of Technological Characteristics:

The Omnia Medical Coupler-A™ Anterior Lumbar Plate System, Omnia Medical Coupler-L™ Lateral Lumbar Plate System 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 8.1: Dimensions and Technological Characteristics Comparison Lumbar Plate Systems

Item	Omnia Medical Coupler-A™ and Coupler-L™ Lumbar Plate Systems	Stryker LITe® Plate System (K221728)	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 Coupler-A™ and Coupler-L™ Lumbar Plate Systems are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the vessels or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); • Pseudoarthrosis; • Spondylolysis; • Spondylolisthesis; • Spinal stenosis; • Tumors; • Trauma (i.e. Fractures or Dislocation) • Deformities (i.e. Scoliosis, Kyphosis or Lordosis)	The LITe® Plate Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc	Equivalent

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	• Failed Previous Fusion	confirmed by patient history and radiographic studies); • Pseudoarthrosis; • Spondylolysis; • Spondylolisthesis; • Spinal stenosis; • Tumors; • Trauma (i.e. Fractures or Dislocation) • Deformities (i.e. Scoliosis, Kyphosis or Lordosis) • Failed Previous Fusion	
Description	The Coupler-A™ and Coupler-L™ Lumbar Plate Systems provide stabilization to the lumbar spine during spinal fusion. These systems include plates, screws, and an instrument set used in the surgical insertion of the implants. The implants are composed of Ti6Al4V ELI Titanium 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 the screws into place with cam screws after insertion. The plates are available in multiple lengths and levels to allow for utilization in fusion operations across L1 to S1 of the lumbar spine. The system instrumentation is manufactured from surgical grade stainless steel and other surgical grade materials. The instrumentation is used in the placement and fixing of the device.	The previously cleared devices consist of a variety of plate systems designed to provide support across implanted levels in the cervical, thoracolumbar, and lumbosacral spine until fusion is achieved.	Equivalent
Plate Sizes-Anterior	Anterior Lumbar Plate, L1-L5, 30mm-40mm Length, 21mm Width Anterior Lumbar Plate, L5-S1, 30mm-40mm Length, 21mm Width	21-37mm 1 Level Universal Plate, 26mm Width 21-37mm 1 Level Sacral Plate, 21/26mm Widths	Equivalent
Plate Thickness-Anterior	3.75mm	3.5mm Universal Plates 4.0mm Sacral Plates	Equivalent
Plate Sizes-Lateral	Lateral Lumbar Plate, L1 – L5, 30mm-40mm Length, 18mm Width	2-Screw Lateral: Length - 16mm-28mm Width – 17 mm 4-Screw Lateral: Length – 18mm-28mm	Equivalent

		Width – 21mm	
Plate Thickness-Lateral	3.75mm	2-Screw Lateral – 4.5 mm 4-Screw Lateral – 4.5 mm	Equivalent
Screw sizes	5.5mm and 6.0mm diameters, varying lengths	5.0mm and 5.5mm diameters, varying lengths	Equivalent
Material	Ti6A14V per ASTM F136	Ti6A14V	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 performs as well as or better than the chosen acceptance criteria.

Conclusion:

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