March 18, 2024

Ulrich Medical USA, Inc.
Eric Lucas
Vice President of Technology
3700 East Plano Parkway
Suite 200
Plano, Texas 75074

Re: K240515
Trade/Device Name: uNion® MAX Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 23, 2024
Received: February 23, 2024

Dear Eric Lucas:

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,

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)*
K240515

Device Name
uNion® MAX Cervical Plate System

Indications for Use *(Describe)*
The uNion MAX Cervical Plate System is intended for anterior fixation of the cervical spine (C2 to T1). The system is to be used to provide stabilization of the anterior cervical spine as an adjunct to fusion for the treatment of degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), pseudarthrosis 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

Date:	23 January 2024
Sponsor:	ulrich medical USA, Inc. 3700 East Plano Pkwy. Suite 200 Plano, TX 75074 regulatory@ulrichmedicalusa.com Phone: 469.238.0800
Sponsor Contact:	Eric Lucas PhD, Vice President of Technology
Proposed Trade Name:	uNion® MAX Cervical Plate System
Common Name:	Anterior cervical plate system
Device Classification:	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation:	888.3060
Device Product Code:	KWQ
Device Description:	uNion MAX is an anterior cervical plate and screw system used to provide mechanical support across implanted level(s) in the cervical spine until fusion is achieved. The components include ∅4.0mm and ∅4.5mm fixed and variable screws having self-tapping, self-drilling or self-drilling/self-tapping tips and one- through four-level plates having lengths from 8mm to 84mm. The plates incorporate a pivoting locking mechanism which functions to block screw backout. The devices are sold non-sterile.
Indications for Use:	The uNion MAX Cervical Plate System is intended for anterior fixation of the cervical spine (C2 to T1). The system is to be used to provide stabilization of the anterior cervical spine as an adjunct to fusion for the treatment of degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), pseudarthrosis or failed previous fusion.
Materials:	uNion MAX components are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136).
Primary Predicate:	uNion Cervical Plate System (ulrich medical USA – K150666)
Predicate/Reference:	MaxAn® Anterior Cervical Plate System (Biomet Spine – K133518)
Performance Data:	ASTM F1717 mechanical testing of the worst case uNion MAX constructs included static and dynamic compression bending and static torsion. The mechanical test results demonstrate that uNion MAX performance is substantially equivalent to the predicate devices.

Technological Characteristics:

uNion MAX Cervical Plate System possesses similar technological characteristics as one or more of the predicate devices. These include:

- basic design (plates and screws configuration),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The fundamental scientific technology of the uNion MAX system is the same as previously cleared devices.

Conclusion:

The uNion MAX Cervical Plate System possesses the same intended use and similar technological characteristics as the predicate devices. Therefore uNion MAX is substantially equivalent for its intended use.