September 14, 2020

Ulrich GmbH & Co. KG
℅ Hans Stover
President & CEO
Ulrich Medical USA
18221 Edison Avenue
Chesterfield, Missouri 63005

Re: K202227
Trade/Device Name: Artus™ cervical plate system
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 7, 2020
Received: August 7, 2020

Dear Hans Stover:

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, M.B.E.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202227

Device Name
Artus™ cervical plate system

Indications for Use *(Describe)*

The Artus™ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date:	7 August 2020
Sponsor:	ulrich GmbH & Co. KG Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0) 731-9654-1304 Fax: +49 (0) 731-9654-2802
Sponsor Contact:	Christoph Ulrich, Managing Partner
510(k) Contact:	Hans Stover ulrich medical USA, Inc. 18221 Edison Avenue Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Trade Name:	Artus™ cervical plate system
Common Name:	Anterior cervical plate system
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Spinal intervertebral body fixation orthosis, 21 CFR 888.3060, KWQ
Device Descripion:	Artus™ is a cervical plate system that provides one- through four-level standard plate designs as well as one- and two-level midline plates. The plates are designed with a blocking mechanism to restrict screw backout. The plating system offers a variety of screw options including self-drilling, self-tapping and self-drilling/self-tapping, all available in either fixed or variable designs and in standard and rescue diameters. The implants are available in a variety of lengths to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	The Artus™ 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:	The Artus™ implants are manufactured from titanium alloy as described by ASTM F136.
Primary Predicate:	uNion™ Cervical Plate System (ulrich medical USA – K150666)
Performance Data:	Mechanical testing of the worst case Artus™ construct was performed according to ASTM F1717 and included dynamic compression bending. The test results demonstrate that Artus™ device mechanical performance is substantially equivalent to the predicate devices. This demonstrates that the Artus™ device performs as well as or better than the primary predicate device.

Technological Characteristics:	The Artus™ cervical plate system possesses the same technological characteristics as the predicate device. These include basic design, material, method of stabilization and anatomic location. Therefore the fundamental scientific technology of the Artus™ cervical plate system devices is the same as previously cleared devices.
Conclusion:	The Artus™ cervical plate system possesses the same intended use and technological characteristics as the predicate devices. Therefore the Artus™ cervical plate system is substantially equivalent for its intended use.