



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ulrich medical USA
Mr. Hans Stover
President & CEO
18221 Edison Avenue
Chesterfield, Missouri 63005

June 22, 2015

Re: K150666
Trade/Device Name: uNion™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 2, 2015
Received: June 4, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K150666

Device Name

uNion™ Cervical Plate System

Indications for Use (Describe)

The uNion™ 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) Summary



Date: 16 June 2015

Sponsor: ulrich medical USA, Inc.
18221 Edison Avenue
Chesterfield, MO 63005
(636) 519-0268 Office
(636) 519-0271 Fax

Contact Person: Hans Stover, President & CEO

Proposed Trade Name: uNion™ 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™ 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 Ø4.0mm and Ø4.5mm fixed and variable screws having self-tapping, self-drilling or self-drilling/self-tapping tips, one- through four-level standard plates having lengths from 10mm to 84mm and one- and two-level midline plates having lengths from 10mm to 46mm. Both the standard and the midline plates incorporate a pivoting insert which functions as an anti-back out mechanism. The devices are sold non-sterile.

Indications for Use: The uNion™ 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™ components are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136).

Predicate Devices: Primary: Zavation Cervical Plate System (Zavation LLC – K130030)
Additional: Zavation Cervical Plate System (Zavation LLC – K112533), MaxAn® Anterior Cervical Plate System (Biomet Spine LLC – K080646, K133518 and Uniplate Anterior Cervical Plate (DePuy Spine – K042544)
Reference: Cervical Spine Locking Plate (CSLP) (Synthes Spine – K945700, K000536, K000742)

Performance Data: Mechanical testing of worst case uNion™ constructs included static and dynamic compression bending and static torsion according to ASTM F1717. The mechanical test results demonstrate that uNion™ performance is substantially equivalent to the predicate devices.

**Technological
Characteristics:**

The uNion™ cervical plate system possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (plate and screw configuration),
- material (titanium alloy),
- sizes (dimensions are comparable to those offered by the predicate systems) and

The fundamental scientific technology of the uNion™ cervical plate system is the same as previously cleared devices.

Conclusion:

The uNion™ cervical plate system possesses the same intended use and technological characteristics as the predicate devices. Therefore uNion™ is substantially equivalent for its intended use.