



Food and Drug Administration  
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December 22, 2016

ulrich GmbH & Co. KG  
% Mr. Hans Stover  
President and CEO  
ulrich medical USA, Inc.  
18221 Edison Avenue  
Chesterfield, Missouri 63005

Re: K161032

Trade/Device Name: neon3™ universal OCT spinal stabilization  
Regulatory Class: Unclassified  
Product Code: NKG, KWP  
Dated: December 2, 2016  
Received: December 5, 2016

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" (21 CFR 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,

**Vincent J. Devlin -S**

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

Enclosure

## Indications for Use

510(k) Number (if known)

**K161032**

Device Name

neon3™ universal OCT spinal stabilization

Indications for Use (Describe)

neon3™ is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

neon3™ is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of 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)

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## **Section 8 – 510(k) Summary**



**Date:** 2 December 2016

**Sponsor:** ulrich GmbH & Co. KG  
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Fax: +49 (0) 731-9654-2802

**Contact Person:** Hans Stover  
ulrich medical USA, Inc.  
18221 Edison Avenue  
Chesterfield, MO 63005  
(636) 519-0268 Office  
(636) 519-0271 Fax

**Trade Name:** neon<sup>3</sup>™ universal OCT spinal stabilization

**Common Name:** Posterior occipital-cervical-thoracic system,  
Cervical Pedicle Screw Spine Fixation

**Device Classification:** Unclassified  
Orthopaedic and Rehabilitation Devices Panel  
Product Code: NKG, KWP

**Submission Purpose:** To add occipital-cervical and cervicothoracic construct components to the cleared neon<sup>3</sup>™ system including rods, plates, screws, hooks, crosslinks and fasteners.

**Device Description:** neon<sup>3</sup>™ is a modular, posterior system used for the surgical stabilization and fixation of the occipital, cervical and thoracic regions of the spine. The system components include longitudinal rods, screw and hook anchors, and interconnecting devices such as anchor- to-rod connectors, and rod-to-rod and screw-to-screw crosslinks.

**Indications for Use:** neon<sup>3</sup>™ is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. neon<sup>3</sup>™ is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of

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|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                       | insufficient duration to permit achievement of fusion.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Materials:</b>                     | neon <sup>3</sup> ™ components are manufactured from Grade 2 titanium (ASTM F67), Ti-6Al-4V titanium alloy (ASTM F136) or Cobalt Chrome (ASTM F1537)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Primary Predicate:</b>             | Synapse Occipital-Cervical-Thoracic (OCT) System (DePuy Synthes Spine, K142838)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Additional Predicates:</b>         | Halifax Interlaminar Clamp (Osteonics– K962314), neon <sup>3</sup> ™ (K150650 – ulrich medical GmbH & Co. KG) and Ascent™ POCT System (Blackstone Medical, K033480 and K073420)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Performance Data:</b>              | <p>Mechanical testing of worst case neon<sup>3</sup>™ craniocervical constructs included static and dynamic compression bending and static torsion according to ASTM F1717 as well as static and dynamic compression bending and static and dynamic torsion per ASTM F2706.</p> <p>The mechanical test results demonstrate that neon<sup>3</sup>™ performance is substantially equivalent to the predicate devices.</p>                                                                                                                                                                                                                                                                         |
| <b>Technological Characteristics:</b> | <p>neon<sup>3</sup>™ possesses technological characteristics similar to one or more of the predicate devices. These include:</p> <ul style="list-style-type: none"><li>x intended use (as described above)</li><li>x basic design (rod-based having screw and/or hook anchors),</li><li>x material (titanium / titanium alloy),</li><li>x sizes (dimensions are comparable to those offered by the predicate systems) and</li></ul> <p>Minor differences in technological characteristics were identified and shown to not raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of neon<sup>3</sup>™ is the same as previously cleared devices.</p> |
| <b>Conclusion:</b>                    | neon <sup>3</sup> ™ possesses the same intended use and technological characteristics as the predicate devices. Therefore neon <sup>3</sup> ™ is substantially equivalent for its intended use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |