May 2, 2023

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

Re: K230614
Trade/Device Name: Cortium™
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: March 3, 2023
Received: March 6, 2023

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 -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)*

K230614

Device Name

Cortium™

Indications for Use *(Describe)*

Cortium is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients 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.

Cortium 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.

In order to achieve additional levels of fixation, Cortium can also be connected to Momentum via transition rods or connectors. Please refer to the Momentum Instructions for Use for a list of indications for use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date:	3 March 2023
Sponsor:	ulrich medical USA, Inc. 18221 Edison Avenue Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Sponsor Contact:	Hans Stover, President & CEO
Proposed Trade Name:	Cortium™
Common Name:	Occipital-cervical-thoracic system
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3075
Regulation Name:	Posterior cervical screw system
Product Code:	NKG
Device Description:	The Cortium system is a posterior occipital-cervical-thoracic (OCT) spinal fixation system. The system components include longitudinal rods, screw anchors, and interconnecting devices such as anchor-to-rod and rod-to-rod connectors, rod-to-rod crosslinks and screw-to-screw crosslinks.
Indications for Use:	Cortium is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients 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. Cortium 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. In order to achieve additional levels of fixation, Cortium can also be connected to Momentum via transition rods or connectors. Please refer to the Momentum Instructions for Use for a list of indications for use.
Materials:	The Cortium implants are manufactured from titanium alloy (ASTM F136), titanium (ASTM F67) or cobalt chrome (ASTM F1537). Instruments are predominantly manufactured from stainless steels per ASTM F899.
Primary Predicate:	neon^3™ (ulrich GmbH & Co KG – K161032)
Additional Predicates:	CerviFix StarLock System (Synthes USA – K994187), neon^3™ (ulrich GmbH & Co KG – K150650), neon system (ulrich GmbH & Co KG – K113346)

Performance Data:

Mechanical testing of worst case Cortium constructs included ASTM F1717 static and dynamic compression bending and static torsion, F1798 tulip pull-off testing and F2706 static and dynamic compression bending and static and dynamic torsion.

The mechanical test results demonstrate that Cortium performance is substantially equivalent.

Technological Characteristics:

Cortium possesses technological characteristics similar to one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (rod-based having screw anchors),
- material (titanium, titanium alloy, CoCr),
- sizes (dimensions are comparable to those offered by the predicate systems)

The fundamental scientific technology of Cortium is the same as previously cleared devices.

Conclusion:

Cortium possesses the same intended use and technological characteristics as the predicate devices. Therefore Cortium is substantially equivalent for its intended use.