August 19, 2022

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

Re: K220696
Trade/Device Name: uCerv Flux™-C 3D Porous Titanium Cervical Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 18, 2022
Received: July 19, 2022

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,

Brent Showalter, Ph.D.
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)*

K220696

Device Name
uCerv Flux™-C 3D Porous Titanium Cervical Interbody

Indications for Use *(Describe)*

The uCerv Flux™-C 3D Porous Titanium Cervical Interbody is indicated for intervertebral body fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The device system is designed for use with supplemental fixation cleared for use in the cervical spine and with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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:	8 March 2022
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
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	uCerv Flux™-C 3D Porous Titanium Cervical Interbody
Common Name:	Cervical interbody fusion device
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, cervical, 888.3080, ODP
Device Description:	The uCerv Flux™-C 3D Porous Titanium Cervical Interbody implants are additively manufactured interbody fusion devices for cervical implantation. The implants are designed having porous surfaces to provide surgical stabilization of the spine. Each interbody has a central cavity that can be packed with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft material and lateral windows for radiographic visualization. The implants are available in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances.
Indications for Use:	The uCerv Flux™-C 3D Porous Titanium Cervical Interbody is indicated for intervertebral body fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The device system is designed for use with supplemental fixation cleared for use in the cervical spine and with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.
Materials:	The uCerv Flux™-C 3D Porous Titanium Cervical Interbody implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001). The instrumentation for implantation is manufactured from medical grade stainless steel per ASTM F899.
Primary Predicate:	Cascadia™ Interbody System (K2M Inc. – K160125)

Performance Data:

Mechanical testing of the worst case uCerv Flux™-C 3D Porous Titanium Cervical Interbody implants included static and dynamic axial compression and static and dynamic torsion according to ASTM F2077. In addition, subsidence according to ASTM F2267 and expulsion tests were performed.

The mechanical test results demonstrate that the uCerv Flux™-C 3D Porous Titanium Cervical Interbody performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The uCerv Flux™-C 3D Porous Titanium Cervical Interbody possesses the same technological characteristics as one or more of the predicate devices. These include:

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

The uCerv Flux™-C 3D Porous Titanium Cervical Interbody is the same as previously cleared devices.

Conclusion:

The uCerv Flux™-C 3D Porous Titanium Cervical Interbody possesses the same intended use and technological characteristics as the predicate devices. Therefore the uCerv Flux™-C 3D Porous Titanium Cervical Interbody is substantially equivalent for its intended use.