May 23, 2024

ulrich medical USA, Inc.
Eric Lucas, Ph.D.
Chief Operating Officer
3700 East Plano Parkway, Suite 200
Plano, Texas 75074

Re: K241396
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: May 14, 2024
Received: May 16, 2024

Dear Dr. Lucas:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241396

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 and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion. The hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. 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.

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510(k) Summary

Date:	14 May 2024
Sponsor:	ulrich medical USA, Inc. 3700 East Plano Pkwy. Suite 200 Plano, TX 75074 regulatory@ulrichmedicalusa.com Phone: 469.238.0800
Sponsor Contact:	Eric Lucas PhD, Chief Operating Officer
Proposed Trade Name:	uCerv Flux™-C 3D Porous Titanium Cervical Interbody
Common Name:	Cervical interbody fusion device
Device Classification:	Class II
Classification Name:	Intervertebral fusion device with bone graft, cervical
Regulation:	888.3080
Device Product Code:	ODP
Submission purpose:	A hyperlordotic implant option is added to the cleared components.
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 and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion. The hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. 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:	uCerv Flux™-C 3D Porous Titanium Cervical Interbody (ulrich medical USA – K220696)

Predicate/Reference: Cascadia™ Interbody System (K2M, Inc. – K160125), LDR Spine Cervical Interbody Fusion System (LDR Spine USA, K091088), INTEGRATE™-C Interbody Fusion System (HAPPE Spine – K222004)

Performance Data: Mechanical testing of the worst case Flux-C devices was relied upon in support of the original uCerv Flux™-C 3D Porous Titanium Cervical Interbody clearance. The testing included static and dynamic axial compression and static torsion according to ASTM F2077 and subsidence according to ASTM F2267. An engineering rationale was used to demonstrate that the additional cervical interbody sizes did not introduce a new worst case.

Mechanical testing of the worst case subject uCerv Flux™-C 3D Porous Titanium Cervical Interbody implants included dynamic torsion according to ASTM F2077 and expulsion tests.

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:

- basic design (additively manufactured interbody 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.