April 15, 2026

ZheJiang Decans Medical Devices Co., Ltd.
Haifeng Liu
RA Manager
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District
Jiaxing City, Zhejiang Province 314031
China

Re: K252774
Trade/Device Name: Uni-C Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: September 2, 2025
Received: March 19, 2026

Dear Haifeng Liu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.

510(k) Number *(if known)*
K252774

Device Name
Uni-C Cervical Cage System

Indications for Use *(Describe)*
The Uni-C Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Uni-C Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. In order to use this system correctly, the Anchoring plate included in this system must be used for supplementary internal fixation.

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

This 510(k) Summary is being prepared in accordance with 21, CFR §807.92.
Date of Preparation: August/30/2025

1. Sponsor Identification

Submitter
ZheJiang Decans Medical Devices Co., Ltd.
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2. Identification of Subject Device

Trade Name: Uni-C Cervical Cage System
Classification Name: Intervertebral body fusion device
Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical
Classification: II
Product Code: OVE
Regulation Number: 21 CFR 888.3080
Review Panel: Orthopedic

3. Identification of predicate device

Trade Name: LDR Spine ROl-C Cervical Cage System
Manufacturer: LDR SPINE USA 13785 Research Boulevard. Suite 200 Austin, TX 78750
510 (k) Number: K150765
Classification Name: Intervertebral body fusion device
Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical
Classification: II
Product Code: OVE
Regulation Number: 21 CFR 888.3080
Review Panel: Orthopedic

4. Indications for Use

The Uni-C Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Uni-C Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. In order to use this system correctly, the Anchoring plate included in this system must be used for supplementary internal fixation.

5. Device Description

The Uni-C Cervical Cage system is a product for cervical interbody fusion fixation surgery, The Uni-C Cervical Cage System is available in a variety of footprints designed to meet varying patient anatomies. The cage accommodates integrated, self-guided, self-locking Anchoring plate designed to provide stability with no instrumentation protruding anterior of the vertebral bodies. The Uni-C cage is an anterior cervical interbody fusion device. The self-guided, curved Anchoring plate are delivered in the plane of the disc through a direct anterior approach.
The raw materials of the cage are PEEK (Polyetheretherketone) and Ta (tantalum) wires, and the raw material of the Anchoring plate is Ti6Al4V.

6. Summary of indication for use and technological characteristics

The subject Uni-C Cervical Cage System is substantially equivalent to the predicate LDR Spine ROI-C Cervical Cage System (K150765) with respect to indications for use and technological characteristics.
The subject device has identical indication for use as the predicate device. The subject device and the predicate device are substantially equivalent with only minor differences in technological characteristics. The differences do not raise new questions of safety and effectiveness.

7. Non-Clinical Test

- **Standard Performance-bench test including:**

Axial Compression Testing per ASTM F2077
Axial Compression Fatigue Testing per ASTM F2077
Static Compression-Shear Testing per ASTM F2077
Compression-shear fatigue testing per ASTM F2077
Static Torsion Testing per ASTM F2077
Torsional fatigue testing per ASTM F2077
Static Axial Compressive Subsidence Testing per ASTM F2267

- **Non-standard Performance-bench testing including**

System Compression Fatigue Testing
System Static Compression Testing
System Static Torsion Testing
System Torsional Fatigue Testing

System Static Launch Testing
Polyurethane Foam Block Insertion Testing (using ASTM F1839 Grade 30 foam block)
System Static Torsion Testing (using ASTM F1839 Grade 15 foam block)
System Static Compression Testing(using ASTM F1839 Grade 15 foam block)

- **Biocompatibility**

The biocompatibility evaluation was performed per ISO10993-1, and biological tests were conducted following applicable standards, the test results demonstrate that the subject device meet biological safety requirements.
In vitro cytotoxicity Test per ISO 10993-5
Skin sensitization Test per ISO 10993-10
Intracutaneous Reactivity Test per ISO 10993-23
Material mediated Pyrogen Test per ISO 10993-11
Chemical Characterization per ISO 10993-18
Toxicological risk assessment of extractable chemicals per ISO 10993-17

- **Sterilization**

The subject device is sterilized using Gamma Radiation. The sterilization validation has been performed in accordance with the principles of
ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11137-3:2017 Sterilization of health care products — Radiation Part 3: Guidance on dosimetric aspects of development, validation and routine control
A sterility assurance level (SAL) of 10^{-6} has been demonstrated. A shelf-life of 5 years has been established based on accelerated aging testing.

8. Animal study and Clinical Test

No animal study data is submitted in this 510(k).

No clinical study data is submitted in this 510(k).

9. Conclusion

The non-clinical performance data submitted in the documents demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device. Based on the information provided in this premarket notification, ZheJiang Decans Medical Devices Co., Ltd. has demonstrated that the proposed Uni-C Cervical Cage System are substantially equivalent to the currently marketed predicates LDR Spine ROI-C Cervical Cage System (K150765).