May 14, 2026

ZheJiang Decans Medical Devices Co., Ltd.
Peiwen Feng
No. 2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District
Jiaxing City, Zhejiang Province 314031
China

Re: K252776
Trade/Device Name: ARIES Anterior Cervical Plate Systems
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 14, 2026
Received: April 15, 2026

Dear Peiwen Feng:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

MAZIAR SHAH-MOHAMMADI -S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252776

Please provide the device trade name(s).

ARIES Anterior Cervical Plate Systems

Please provide your Indications for Use below.

The ARIES Anterior Cervical Plate Systems is intended for anterior interbody screw fixation from C2-T1 in the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:
1) Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2) Trauma (including fractures)
3) Tumors
4) Deformity (defined as kyphosis, lordosis, or scoliosis)
5) Pseudarthrosis, and/or
6) Failed previous fusions

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

ARIES Anterior Cervical Plate Systems

1. Submitter

ZheJiang Decans Medical Devices Co., Ltd.
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Telephone:+86 18758326652
Email:pwfeng@decansmd.com
Date of Preparation:August/20/2025
Prepared in accordance with 21CFR807.92

2. Identification of subject device

Trade name: ARIES Anterior Cervical Plate Systems
Regulation number: 21CFR888.3060
Regulation name: Spinal intervertebral body fixation orthosis
Regulation class: Class II
Product code: KWQ
Common name: appliance, fixation, spinal intervertebral body
Review panel: Orthopedic
Material: Ti6Al4V per ISO 5832-3
Patient contact:Bone and surrounding tissue
Contact duration:Permanent, >30 days
Sterilization method: Moist heat sterilization
Environment of Use: Healthcare facility/Hospital
Single Use: yes
Provided status: non-sterile

3. Identification of predicate device(s)

- **Primary predicate device**

K021461-ATLANTIS™ Anterior Cervical Plate System
Regulation number: 21CFR888.3060
Regulation name: Spinal intervertebral body fixation orthosis
Regulation class: Class II

Product code: KWQ
Common name: appliance, fixation, spinal intervertebral body
Review panel: Orthopedic

- **Additional predicate device:**

K130640-ATLANTIS™ Anterior Cervical Plate System
Regulation number: 21CFR888.3060
Regulation name: Spinal intervertebral body fixation orthosis
Regulation class: Class II
Product code: KWQ
Common name: appliance, fixation, spinal intervertebral body
Review panel: Orthopedic

K103491-SKYLINE® Anterior Cervical Plate System
Regulation number: 21CFR888.3060
Regulation name: Spinal intervertebral body fixation orthosis
Regulation class: Class II
Product code: KWQ
Common name: appliance, fixation, spinal intervertebral body
Review panel: Orthopedic

K231090-ZEVO™ Anterior Cervical Plate System
Regulation number: 21CFR888.3060
Regulation name: Spinal intervertebral body fixation orthosis
Regulation class: Class II
Product code: KWQ
Common name: appliance, fixation, spinal intervertebral body
Review panel: Orthopedic

4. Device description

The ARIES Anterior Cervical Plate Systems consist of titanium plates of various lengths and a range of screws.The screws are inserted into the cervical vertebrae through the holes on the fixation plates for fixation. The titanium plate includes a screw anti-extraction locking mechanism, which covers the head of the screw to reduce the possibility of screw withdrawal.The components of the device are made of titanium alloy(Ti6Al4V) per ISO 5832-3, and are supplied in non-sterile form.

5. Indication for use

The ARIES Anterior Cervical Plate Systems is intended for anterior interbody screw fixation from C2-T1 in the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

1) Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2) Trauma (including fractures)
3) Tumors
4) Deformity (defined as kyphosis, lordosis, or scoliosis)
5) Pseudarthrosis, and/or
6) Failed previous fusions

6. Substantial equivalence comparison

We did comparisons and identified similarities and differences of the subject device to the legally marketed predicate devices with respect to Indication for use, technological characteristics following the FDA guidance *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* (issued on July 2014).

The subject device ARIES Anterior Cervical Plate Systems and predicate devices are equivalent in the indication for use and anatomical site, they are same in patient population, patient contact type, contact duration, component, mechanism of action, single use, SAL. Any technological similarities or differences between the subject and predicate devices are considered minor and do not raise any new issues of safety or effectiveness.

7. Non-clinical Test summary

- **Standard performance test**

Static Compression Bending Test per ASTM F1717-21
Static Torsion Test per ASTM F1717-21
Dynamic Compression Bending Fatigue Test per ASTM F1717-21

Performance criteria proposed in the FDA Guidance *Spinal Plating Systems-Performance Criteria for Safety and Performance Based Pathway issued on September 20,2019,* is used to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of the predicate device. Test results were satisfactory and met acceptance criteria.

- **Sterilization efficacy validation**

The recommended sterilization method for subject device is moist heat sterilization. The sterilization validation has been performed on an representative product in accordance with ISO 17665:2024. A sterility assurance level (SAL) of 10^{-6} has been demonstrated.

- **Biocompatibility**

The biocompatibility evaluation was performed per ISO10993-1, and biological tests were conducted on an representative products following applicable standards.Through test and evaluation, the subject is determined as biocompatible. Tests included:
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

8. Performance-Clinical or animal

The subject of this premarket submission, did not require clinical study data or animal study data to support substantial equivalence.

9. Referenced FDA guidance

- Guidance for Industry and FDA Staff: Spinal System 510(k)s (issued on May ,2004)
- Format for Traditional and Abbreviated 510(k)s Guidance (issued on December , 2019)
- Electronic Submission Template for Medical Device 510(k) Submissions (issued on October, 2023)
- Use of International Standard ISO 10993-1,“Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process” (issued on September, 2023)
- Chemical Analysis for Biocompatibility Assessment of Medical Device draft guidance (issued on September, 2024)
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (issued on July, 2014)
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions (issued on December 2019)

10. Conclusion

The subject device is substantially equivalent to the predicate devices. The identified similarities or differences does not raise any new issues of safety or effectiveness. ZheJiang Decans Medical Devices Co.,Ltd. believes that ARIES Anterior Cervical Plate Systems is as safe and effective, and perform as well as the legally marketed predicate devices.