May 27, 2026

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

Re: K252930
Trade/Device Name: AQUA Laminoplasty Systems
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: September 15, 2025
Received: September 15, 2025

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 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] 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

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.	K252930

Please provide the device trade name(s).

AQUA Laminoplasty Systems

Please provide your Indications for Use below.

The AQUA Laminoplasty Systems is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The AQUA Laminoplasty Systems is used to hold the graft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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

This 510(k) Summary has been prepared in accordance with 21 CFR §807.92.
Date of Preparation:15 September 2025

1. Submitter and Contact

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

Trade name: AQUA Laminoplasty Systems
Regulation number: 21CFR888.3050
Regulation name: Spinal interlaminal fixation orthosis
Regulation class: Class II
Product code: NQW
Common name: Orthosis, Spine, Plate, Laminoplasty, Metal
Review panel: Orthopedic
Materials: Ti6Al4V , Unalloyed titanium (Grade 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**

Product Name	CENTERPIECE^{TM} Plate Fixation System

Manufacturer	Medtronic Sofamor Danek
510 (k)	K212428
Regulation number	21CFR888.3050
Regulation name	Spinal interlaminal fixation orthosis
Regulation class	Class II
Product code	NQW
Common name	Orthosis, Spine, Plate, Laminoplasty, Metal
Review panel	Orthopedic

- **Additional predicate device**

Product Name	MOUNTAINEER® Laminoplasty System	NuVasive® Camber Laminoplasty System	Synthes Arch™ Fixation System (AFS)
510 (k)	K091994	K191169	K032534
Manufacturer	DePuy Spine, Inc.	NuVasive, Incorporated	Synthes Spine
Regulation number	21CFR888.3050		
Regulation name	Spinal interlaminal fixation orthosis		
Regulation class	Class II		
Product code	NQW		
Common name	Orthosis, Spine, Plate, Laminoplasty, Metal		
Review panel	Orthopedic		

4. Device description

The AQUA Laminoplasty Systems consist of a variety sized Bone Screws and titanium plates. Fixation is achieved through titanium plate support and screw fixation. Plates are made of unalloyed titanium (Grade 3) per ISO 5832-2, while Bones Screws are made of titanium alloy (Ti6Al4V) per ISO 5832-3. The subject device will be delivered non-sterile.

5. Indications for Use

The AQUA Laminoplasty Systems is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The AQUA Laminoplasty Systems is used to hold the graft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

6. Substantial of Indication for Use and Technological

Characteristics

The subject AQUA Laminoplasty Systems is substantially equivalent to the predicate devices with respect to indications for use and technological characteristics.

The subject device has identical indication for use, surgical approach and anatomical site as the predicate devices. The subject device and the predicate devices are substantially equivalent with only minor differences in technological characteristics. The differences do not raise new questions of safety and effectiveness.

7. Test Summary

- **Non-standard Mechanical Testing**

A series of side-by-side tests have been conducted on subject and predicates, in order to support mechanical equivalence, including the following:

Axial Pullout Performance Testing

Customized Static Compression-Bend Testing

Customized Compression-Bend Fatigue Testing

- **Sterilization efficacy validation**

The recommended sterilization method for subject device is moist heat sterilization. The sterilization efficacy 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.

8. Performance-Clinical or Animal

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

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

9. Conclusion

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