July 31, 2026

Zsfab, Inc.
% Hannah Taggart
Engineer & Regulatory Specialist
ATS Colorado Springs
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K261451
Trade/Device Name: ZSAlign Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: July 10, 2026
Received: July 10, 2026

Dear Hannah Taggart:

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,

BRENT SHOWALTER -S

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)*

K261451

Device Name

ZSAlign Cervical Interbody System

Indications for Use *(Describe)*

The ZSAlign Cervical Interbody System is a cervical interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2–T1) at multiple contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment prior to treatment with this device.

The ZSAlign Cervical Interbody System consists of an interbody cage used in conjunction with an anterior cervical plate, available in 2-, 3-, and 4-hole configurations, and bone screws. The interbody cage component is not intended for cage-only use and must be implanted as part of the cage-plate-screw construct. Plate and bone screw fixation are required for every use of this device.

The interbody cage is to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, or a bone void filler cleared by FDA for use in intervertebral body fusion, to facilitate fusion. The ZSAlign Cervical Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2–T1), with bone screw fixation at each treated level.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

Submitter's Name:	ZSFab, Inc.
Submitter's Address:	96 Clematis Avenue, Suite 2F Waltham, Massachusetts 02453
Submitter's Telephone:	617-468-8665
Contact Person:	Hannah Taggart, MS, RAC ATS Colorado Springs (Empirical Technologies) 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	May 1, 2026
Trade or Proprietary Name:	ZSAlign Cervical Interbody System
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical Intervertebral Fusion Device with Bone Graft, Cervical
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVE, ODP
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ZSAlign Cervical Interbody System is a spinal intervertebral body fusion device designed to provide mechanical support to the cervical spine while arthrodesis occurs. The subject device implants include interbody cages, bone screws, and an anterior plate. The ZSAlign Cervical Interbody System cage implants are additively manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F3001 and supplied sterile. The screws and plates are manufactured from Ti-6Al-4V ELI per ASTM F136 and provided non-sterile. The ZSAlign Cervical Interbody System is offered in a variety of styles and sizes to accommodate the patient's anatomical needs and is implanted from an anterior approach.

INDICATIONS FOR USE

The ZSAlign Cervical Interbody System is a cervical interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2–T1) at multiple contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment prior to treatment with this device.

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The interbody cage is to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, or a bone void filler cleared by FDA for use in intervertebral body fusion, to facilitate fusion.

The ZSAlign Cervical Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2–T1), with bone screw fixation at each treated level.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Structure and Function
- Materials of manufacture
- Sterility
- Sizes
- Manufacturing and Biocompatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K212904	SeaSpine WaveForm™ C Interbody System	SeaSpine Orthopedics	OVE, ODP	Primary
K242734	ZSFab Cervical Interbody System	ZSFab, Inc.	ODP, MAX	Additional
K250486	Skyway Anterior Cervical Plate System	Kyocera Medical Technologies, Inc.	OVE, KWQ	Additional

There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

PERFORMANCE DATA

The ZSAlign Cervical Interbody System has been tested in the following test modes:

- Static Axial Compression per ASTM F2077
- Dynamic Axial Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Dynamic Compression Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Dynamic Torsion per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion
- Screw Backout

The results of this non-clinical testing show that the strength of the ZSAlign Cervical Interbody System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the ZSAlign Cervical Interbody System is substantially equivalent to the predicate device.