



April 24, 2026

ZSFab, Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Applied Technical Services (Empirical Technologies)
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K260549

Trade/Device Name: ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: February 18, 2026
Received: February 18, 2026

Dear Nathan Wright:

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

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.

K260549

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Please provide the device trade name(s).

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ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System

Please provide your Indications for Use below.

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The ZSFab Cervical Interbody System is intended for anterior interbody fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The ZSFab Cervical Interbody System is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by clinical image (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The ZSFab Cervical Interbody System is designed for use 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 and to be used with supplemental fixation cleared for use in the cervical spine. Implants having a lordotic angulation $>10^{\circ}$ are required to be used with an anterior cervical plate as the form of supplemental fixation.

The ZSFab Lumbar Interbody System is intended for lumbar interbody fusion. The devices are indicated for use at one or two contiguous levels in the lumbar spine from L2-S1, in skeletally mature patients who have had at least six months of non-operative treatment. The ZSFab Lumbar Interbody System is indicated to treat lumbar degenerative disc disease (DOD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). ODD is defined as back pain of discogenic origin with degeneration of the disc confirmed by imaging studies (radiographs, CT, MRI). Additionally, the ZSFab Lumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The ZSFab lumbar Interbody System is designed for use 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 and to be used with supplemental fixation cleared for use in the lumbosacral spine.

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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:	Nathan Wright, MS, RAC Applied Technical Services (Empirical Technologies) 1-719-351-0248 nawright@atslab.com
Date Summary was Prepared:	February 18, 2026
Trade or Proprietary Name:	ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System
Device Classification Name:	Intervertebral Fusion Device with Bone Graft, Cervical Intervertebral Fusion Device with Bone Graft, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	ODP, MAX
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System include additively manufactured interbody fusion devices for cervical and lumbar implantation respectively to stabilize the spine and facilitate fusion. The ZSFab Cervical Interbody System implants are designed with lattice structures to provide surgical stabilization of the spine. The lattices have near-elliptical pores with minor axis length of 500 µm to 920 µm and major axis length of 810 µm to 1390 µm. The ZSFab Lumbar Interbody System implants are designed as a solid frame that includes lattice structures to provide surgical stabilization of the spine. The lattices have near-elliptical pores with axis lengths of 610 µm to 1180 µm. The endplates are featured with teeth design and stochastic lattice structures with average pore size of 620 µm to 710 µm. Each cervical and lumbar interbody has a bone graft window that can be packed with bone graft material. The implants are available in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances. The implants are additively manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F3001 and supplied sterile.

The purpose of this 510(k) Submission is to expand production of these implants to an additional 3D printer model.

INDICATIONS FOR USE

The ZSFab Cervical Interbody System is intended for anterior interbody fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The ZSFab Cervical Interbody System is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by clinical image (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The ZSFab Cervical Interbody System is designed for use 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 and to be used with supplemental fixation cleared for use in the cervical spine. Implants having a lordotic angulation >10° are required to be used with an anterior cervical plate as the form of supplemental fixation.

The ZSFab Lumbar Interbody System is intended for lumbar interbody fusion. The devices are indicated for use at one or two contiguous levels in the lumbar spine from L2-S1, in skeletally mature patients who have had at least six months of non-operative treatment. The ZSFab Lumbar Interbody System is indicated to treat lumbar degenerative disc disease (DOD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). ODD is defined as back pain of discogenic origin with degeneration of the disc confirmed by imaging studies (radiographs, CT, MRI). Additionally, the ZSFab Lumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The ZSFab lumbar Interbody System is designed for use 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 and to be used with supplemental fixation cleared for use in the lumbosacral spine.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are the same between the subject and predicates:

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

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Type
K242734	ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System	ZSFab, Inc.	ODP, MAX	Primary
K252610	ZSFab Lumbar Interbody System	ZSFab, Inc.	MAX	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 ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System have been tested in ASTM F2077 dynamic axial compression, ASTM F2077 dynamic compression shear, and ASTM F2077 dynamic torsion to confirm the subject does not create a worst-case compared to the previously cleared devices.

The results of this non-clinical testing show that the subject ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System are substantially equivalent to legally marketed predicate devices.

CONCLUSION

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