November 25, 2025

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

Re: K252610
Trade/Device Name: ZSFab Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 10, 2025
Received: November 10, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

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.	K252610

Please provide the device trade name(s).

ZSFab Lumbar Interbody System

Please provide your Indications for Use below.

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 (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD 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 (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252610 - 510(K) SUMMARY

Submitter's Name: Submitter's Address: Submitter's Telephone:	ZSFab, Inc. 96 Clematis Avenue, Suite 2F Waltham, Massachusetts 02453 617-468-8665
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies (an ATS Company) 1-719-351-0248 nawright@atslab.com
Date Summary was Prepared:	November 10, 2025
Trade or Proprietary Name:	ZSFab Lumbar Interbody System
Device Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic – Spinal Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ZSFab Lumbar Interbody System includes additively manufactured interbody fusion devices for lumbar implantation. The 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 850µm to1180µm. The endplates are featured with teeth design and stochastic lattice structures with average pore size of 620µm to 710µm. Each lumbar interbody has a central cavity for 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) is to introduce a line extension of the P-TLIF configuration with additional sizes.

INDICATIONS FOR USE

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 (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD 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 nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Structure and Function
- Material of Manufacture
- Size Options
- Manufacturing and Biocompatibility
- Sterility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K242734	ZSFab Lumbar Interbody System	ZSFab, Inc.	Primary
K221858	ZSFab Lumbar Interbody System	ZSFab, Inc.	Additional
K172816	TiGer Shark System	Choice Spine, LP	Additional
K133614	Aleutian IBF System	K2M, Inc.	Additional

PERFORMANCE DATA

The subject ZSFab Lumbar Interbody System was evaluated through finite element under ASTM F2077 axial compression and compression shear loading conditions and tested in dynamic axial compression and compression shear to verify that the mechanical testing under of the ZSFab Lumbar Interbody System under K242734 was the worst-case compared to subject implants. The subject ZSFab Lumbar Interbody System was also tested in expulsion.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the subject ZSFab Lumbar Interbody System is substantially equivalent to the predicate devices.