August 18, 2023

ZSFab Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K232150
Trade/Device Name: ZSFab Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 18, 2023
Received: July 19, 2023

Dear Dr. Warden:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232150

Device Name

ZSFab Cervical Interbody System

Indications for Use *(Describe)*

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 imaging studies (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.

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.

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Section 7 – 510(k) Summary

Date:	18 July 2023
Sponsor:	ZSFab Inc. 96 Clematis Ave, Suite 2F Waltham, MA 02453 Office: 617.468.8665
Sponsor Contact:	Xuewei Ma, R&D Director
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	ZSFab Cervical Interbody System
Common Name:	Cervical interbody fusion device
Regulatory Class:	Class II
Regulation Name:	Intervertebral fusion device with bone graft, cervical
Regulation Number:	21 CFR 888.3080
Product Code:	ODP
Submission Purpose:	The subject 510(k) adds sizes to the ZSFab Cervical Interbody System.
Device Description:	The ZSFab Cervical Interbody System includes additively manufactured interbody fusion devices for cervical implantation. The implants are designed with lattice structures to provide surgical stabilization of the spine. The lattices have near-elliptical pores with minor axis length of 500-920µm and major axis length of 810-1390µm. Each 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.
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 imaging studies (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.
Materials:	The ZSFab Cervical Interbody System implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001).
Primary Predicate:	ZSFab Cervical Interbody System (ZSFab Inc. – K202488)
Additional Predicates:	Cascadia™ Interbody System (K2M Inc. – K160125), INTEGRATE™-C Interbody Fusion System (HAPPE Spine – K222004)

Performance Data:

Mechanical testing of the worst case ZSFab Cervical Interbody System was relied upon in support of the original ZSFab Cervical Interbody System clearance. The testing included static and dynamic axial compression and static and dynamic torsion according to ASTM F2077, subsidence according to ASTM F2267 and expulsion. An engineering rationale was used to demonstrate that the additional cervical interbody sizes did not introduce a new worst case.

Sterilization validations were successfully performed to meet AAMI ST79 parameters.

Technological Characteristics:

The ZSFab Cervical Interbody System possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (additively manufactured structure),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The ZSFab Cervical Interbody System is the same as previously cleared devices.

Conclusion:

The ZSFab Cervical Interbody System possesses the same intended use and technological characteristics as the predicate devices. Therefore the ZSFab Cervical Interbody System is substantially equivalent for its intended use.