



November 7, 2024

ZSFab
% Danielle Besal
Principal Consultant
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K242734

Trade/Device Name: ZSFab Cervical Interbody System; 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: September 10, 2024
Received: September 10, 2024

Dear Danielle Besal:

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

510(k) Number (if known)

K242734

Device Name

ZSFab Cervical Interbody System;

ZSFab Lumbar 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 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 (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.

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.

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510(k) Summary*ZSFab Cervical and Lumbar Interbody Systems**October 31, 2024*

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Trade Name: ZSFab Cervical Interbody System; ZSFab Lumbar Interbody System
Common Name: Intervertebral body fusion device
Classification: Class II
Regulation Number: 888.3080 Intervertebral Fusion Device
Panel: Orthopedic
Product Code: ODP, MAX
Predicate Devices: K232150, K202488: ZSFab Cervical Interbody System
K221858: ZSFab Lumbar 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. 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 610-1000µm. The endplates are featured with teeth design and stochastic lattice structures with average pore size of 620-710µm. 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.

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 $>10^{\circ}$ 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 (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.

Substantial Equivalence:

The ZSFab Cervical and Lumbar Interbody Systems are substantially equivalent to the predicate devices (K232150, K202488, K221858). The subject and predicate devices have the identical indications for use, designs, and materials. The technological characteristics of the subject devices as manufactured at the new location are identical to those of the predicate devices, as confirmed by mechanical testing.

Performance Testing:

The subject cervical cages were tested for static and dynamic axial compression (ASTM F2077), static and dynamic torsion (ASTM F2077), subsidence (ASTM F2267), and expulsion (ASTM F-04.25.02.02). The subject lumbar cages were tested in accordance with ASTM F2077 for static and dynamic axial compression and static and dynamic compression shear. The lumbar cages were also tested for subsidence per ASTM F2267 and expulsion per ASTM F-04.25.02.02. Mechanical test results demonstrated the subject devices are substantially equivalent to the predicate devices.

Conclusion:

The ZSFab Cervical and Lumbar Interbody Systems are considered substantially equivalent to the predicate devices (K232150, K202488, K221858).