June 2, 2022

Zavation Medical Products, LLC
Mr. Matt Jones
Design Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

Re: K220581
Trade/Device Name: Zavation eZspand™ Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 3, 2022
Received: May 4, 2022

Dear Mr. Jones:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220581

Device Name
Zavation eZspand™ Interbody System

Indications for Use *(Describe)*
The Zavation eZspand™ Interbody System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation eZspand™ Interbody System implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended to be used in patients who have had six months of non-operative treatment.

The Zavation eZspand™ Interbody System implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including the Zavation Spinal System.

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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K220581
510K Summary

Date:	May 3, 2022
Submitter:	Zavation Medical Products, LLC 220 Lakeland Pkwy Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact Person:	Matt Jones
Type of 510(k) submission:	Traditional
Trade name:	Zavation eZspand™ Interbody System
Common name:	Intervertebral Body Fusion Device
Classification regulation:	Intervertebral body fusion device (21 CFR 888.3080)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	MAX
Basis for submission:	Addition of new components
Prior Submissions:	K191339

Device Description:
The Zavation eZspand™ Interbody System devices are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The implants are provided in a shape that accommodates a posterior, transforaminal or lateral approach to the lumbar spine. After insertion, the implant can be continuously expanded, within in the limitations of the design, to the desired height to suit the individual anatomical conditions of the patient. The devices are available in various footprints and geometric options to fit the anatomical needs of a wide variety of patients. The implants include an opening through the superior and inferior endplates of the device to facilitate fusion. The posterior opening of the device allows for the packing of autogenous bone graft material post expansion. Serrations on

the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

Intended Use:
The Zavation eZspand™ Interbody System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation eZspand™ Interbody System implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended to be used in patients who have had six months of non-operative treatment.

The Zavation eZspand™ Interbody System implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including the Zavation Spinal System.

Materials:
The interbody components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136, cobalt chrome alloy (Co-28Cr-6Mo) as described by ASTM F1537, and medical grade PEEK Zeniva ZA-500 or Magnolia PEEK as described by ASTM F2026.

Primary Predicate Device:
K191339 Zavation eZspand™ Interbody System [Zavation]

Additional Predicate Device:
K200084 Zavation IBF System [Zavation]
K192115 Sable™ Expandable Spacer [Globus]

Reference Device:
K132126 Zavation Fenestrated Facet Screw System [Zavation]
K211113 Zavation Spinal System [Zavation]

Technological Characteristics:
The Zavation eZspand™ Interbody System possesses the same technological characteristics as the predicate devices, including: basic design (lumbar interbody fusion device of various footprints and lordosis with an expansion mechanism that allows for continuous height adjustment within the design limitations of the device), sizes (length, width and minimum/maximum height), materials, mechanical safety and performance, and intended use.

Performance Data:
Biomechanical test results demonstrated that the Zavation eZspand™ Interbody system is substantially equivalent to the predicate devices. Testing was performed in accordance with:

- ASTM F2077, Test Methods for Intervertebral Body Fusion Devices
    - Static Axial Compression
    - Dynamic Axial Compression

    - Static Shear
    - Dynamic Shear
- ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM Draft F04.25.02.02, Static Pushout Test Method for Intervertebral Body Fusion Devices.

Conclusion:

The Zavation eZspand™ Interbody System devices are similar to the predicate systems with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate devices.