April 12, 2022

Zavation Medical Products, LLC
Katie Motley
Design Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

Re: K212811
Trade/Device Name: Ti3Z Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 17, 2022
Received: March 18, 2022

Dear Katie Motley:

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, 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)*
K212811

Device Name
Ti3Z Lumbar Interbody System

Indications for Use *(Describe)*

When used as a lumbar intervertebral body fusion device, the Zavation Ti3Z Interbody implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF 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 lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation Ti3Z Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw 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.

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510K Summary

Date:	September 1, 2021
Submitter:	Zavation Medical Products, LLC 220 Lakeland Pkwy Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Katie Motley
Type of 510(k) submission:	Traditional
Trade name:	Ti 3Z Lumbar Interbody System
Common name:	Intervertebral Body Fusion Device
Classification regulation:	888.3080 (MAX)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	MAX

Device Description:
The Zavation Ti3Z Lumbar Interbody System implants are offered in five main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF with the choice of two different material options, allowing for multiple surgical technique options. Ti3Z Lumbar implants are additively manufactured from medical grade Ti64ELI powder by way of laser sintering (ASTM F3001); Ti3Z-PEEK Lumbar implants have an exterior that is manufactured from medical grade PEEK (polyetheretherketone) with tantalum beads or pins embedded in the implants to allow for radiographic visualization. Ti3Z-PEEK implants also contain an interior titanium insert manufactured by way of laser sintering (ASTM F3001). The ends of the Ti3Z-PEEK implants have machined teeth which are designed to engage with the vertebral body end plates.

The Zavation Ti3Z Lumbar Interbody implants are available in a range of heights, widths, and lengths as well as parallel and lordotic angled implants, to accommodate variations in patient's anatomy. The internal body of the implants have a porous structure wile the external edges of the implants have a solid, roughened surface designed to engage with the vertebral body end plates. All implants will be provided sterile.

Purpose of 510K
Addition of the Ti3Z-PEEK Lumbar Interbody device.

Indications for Use:
When used as a lumbar intervertebral body fusion device, the Zavation Ti 3Z Interbody implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF 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 lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation Ti 3Z Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System.

Materials:
The devices are manufactured from medical grade Titanium Ti6ALV 4ELI alloy (ASTM F3001-14) **OR** medical grade PEEK (ASTM F560) with Tantalum markers (ASTM F2026) and a medical grade Titanium TI6ALV 4ELI allow (ASTM F3001-14) insert and pin (ASTM F136).

Predicate Device:
Primary - Zavation IBF System, Zavation LLC (K181246)
Additional – MiRus 3D Printed Lumbar Interbody Fusion System (K191906)
Additional – Zavation Ti3Z Lumbar Interbody System (K180076)
Additional – Zavation Ti3Z Cervical Interbody System (K202398)

Technological Characteristics:
The Zavation Ti 3Z Interbody System possesses similar technological characteristics as the predicates. These include: basic design (material, rectangular shape with bulleted nose, and graft windows for packing autogenous bone); sizes (similar heights, widths, lengths, and lordotic angles); and intended use (as described above).

The subject device is identical in surgical technique and instrumentation to the primary predicate device cleared in (K181246) and additional predicate (K180076). The difference to the Zavation Ti3Z Lumbar Interbody System is the addition of a Titanium (ASTM F3001) and PEEK combination implant with the titanium serving as an interior insert. Zavation Ti3Z-PEEK Lumbar possesses the same technological characteristics as the primary predicate and additional predicate. These include similar heights, widths, lengths, and intended use.

Performance Data:
Mechanical test results demonstrated that the Zavation Ti3Z-PEEK Lumbar spacer 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 Compression Shear
  - Dynamic Compression Shear
  - Static Torsion
- ASTM F2267
  - Subsidence
- Expulsion

Process Validation test results demonstrate that the Zavation Ti3Z Lumbar Interbody System (K180076), Ti3Z Cervical Interbody System (K202398) and Zavation IBF System (K181246) are free from any possible contaminants and the cleaning process is adequate for implants to be provided sterile. The Zavation TI3Z-PEEK Lumbar spacers' manufacturing, post processing, cleaning, sterilization, and packaging are identical to that of the Zavation IBF System (K181246), Zavation Ti3Z Cervical System (K202398), and Zavation Ti3Z Lumbar System (K180076) and fall under current validated procedures.

- ASTM F 2847-10, Standard Practice for Reporting Assessment of Residues on Single Use Implants
  - Gravimetric Analysis, ASTM F 2459-12
  - Cytotoxicity, ISO 10993-5: 2009
  - Total Organic Carbon
  - Limulus Amebocyte Lysate (LAL) (Endotoxin)

Basis for Substantial Equivalence:

The Zavation Ti3Z-PEEK lumbar 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 spacers to the predicate devices and is therefore safe and effective for its intended use.