



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

July 27, 2018

Re: K180076  
Trade/Device Name: Ti 3Z Interbody System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: June 26, 2018  
Received: June 27, 2018

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K180076

Device Name

Ti 3Z Interbody System

Indications for Use (Describe)

When used as a lumbar intervertebral body fusion device, the Zavation Ti 3Z Interbody System implants are indicated for spinal fusion procedures to be used with autogenous 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.

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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## 510K Summary

Date: January 9, 2018

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 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 Ti 3Z Interbody implants offer a variety of heights, widths and lengths. There are five main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF. The different configurations allow for multiple surgical technique options. The implants are additively manufactured from medical grade Titanium Ti64ELI powder by way of laser sintering.

The Zavation Ti 3Z Interbody implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. The internal body of the implants have a porous structure while the external edges of the implants have a solid, roughened surface designed to engage with the vertebral body end plates. Both porous and solid aspects of each implant are printed simultaneously.

### **Purpose of 510K:**

New 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 autogenous 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 Ti64ELI (ASTM F3001-14).

**Predicate Device:**

Primary -Zavation IBF System, Zavation LLC (K112664)

Additional – Stryker Spine Tritanium® PL Cage (K152304)

Additional – K122097 Globus Medical Patriot® Spacers (Continental™ ALIF and TransContinental®)

**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).

**Performance Data:**

Mechanical test results demonstrated that the Zavation Ti 3Z 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 Compression Shear
  - Dynamic Compression Shear
  - Static Torsion
  - Subsidence
  - Expulsion

Process Validation test results demonstrate that the Zavation Ti 3Z Interbody System is free from any possible contaminants and the cleaning process is adequate for implants to be provided sterile.

- 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 Ti 3Z Interbody 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.