June 14, 2023

Zavation Medical Products, LLC
Frankie Cummins
Chief Engineer
3670 Flowood Dr.
Flowood, Mississippi 39232

Re: K230731
Trade/Device Name: Zavation ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 15, 2023
Received: March 16, 2023

Dear Frankie Cummins:

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,

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

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)*

Device Name
Zavation ALIF System

Indications for Use *(Describe)*

The Zavation ALIF System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation ALIF System is to be filled with autogenous bone graft material.

The Zavation ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar 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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510K Summary

Date:	Jun 14, 2023
Submitter:	Zavation Medical Products, LLC 3670 Flowood Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Frankie Cummins
Type of 510(k) submission:	Traditional
Trade name:	Zavation ALIF System
Common name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification regulation:	21 CFR 888.3080 Intervertebral body fusion device
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	OVD
Basis for submission:	NEW

Purpose: The purpose of this submission is to request clearance for the Zavation ALIF System.

Device Description:
The Zavation ALIF System includes a spacer, plate, screws, and anchors. The spacer component is assembled to an interbody plate and implanted anteriorly. The spacer components are available in a variety of materials, depths, widths, and heights. The plate component includes three or four holes for inserting bone screws or anchors. The plate component also includes a lock at each hole. The bone screws are available in a variety of diameters and lengths. The anchors are available in a variety of lengths. The interbody plate components are available in a variety of heights.

Indications for Use:
The Zavation ALIF System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation ALIF System is to be filled with autogenous bone graft material.

The Zavation ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar spine.

Materials:
The Zavation ALIF System components are manufactured from medical grade titanium alloy Ti-6Al-4V ELi (ASTM F136 and ASTM F3001), OR medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum (ASTM F560) alloy position markers. The PEEK implants are available with or without titanium plasma coating on the device. The plasma coating is made from commercially pure titanium per (ASTM F1580).

Primary Predicate Device:
K170157 Independence Spacers [Globus]

Additional Predicate Device:
K142271 Zavation Z-Link Lumbar [Zavation]
K212811 T1 3Z Lumbar Interbody System [Zavation]
K200084 Zavation IBF System [Zavation]
K211306 LABYRINTH [Zavation]
K214047 El Capitan Anterior Interbody Fusion System [Astura Medical]

Performance Data:
A comparison of the test results indicates that the Zavation ALIF System exhibited equal or better performance than predicates in static axial compression, dynamic axial compression, static shear, dynamic shear, subsidence, and expulsion per ASTM F2077 and ASTM F2267.

Titanium coating properties are identical to that of the Zavation IBF System (K200084) that was evaluated using standards: ASTM F1147, Tensile Bond Strength; ASTM F1044, Static Shear Strength;

ASTM F1160, Shear Fatigue Strength; ASTM F1854, Metallurgical Testing; and ASTM F1978, Abrasion Test.

The porous titanium spacers' manufacturing, post processing, cleaning, sterilization, and packaging are identical to that of the Ti 3Z Lumbar Interbody System (K212811).

Technological Characteristics:

The subject device is similar in indications for use, surgical technique, and instrumentation to the primary predicate device cleared in (K170157). The specifications of the titanium coating are identical to that of the additional predicate device cleared in (K200084). The specifications of the porous PEEK structure on the endplates are identical to that of the additional predicate device cleared in (K211306). The specifications of the porous Titanium structure are identical to that of the additional predicate device cleared in (K212811). The Zavation ALIF System possesses the same technological characteristics as the predicates. These include similar heights, widths, lengths, and intended use.

Substantial Equivalence Conclusion:

The Zavation ALIF 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.