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

July 12, 2021

Re: K211113
Trade/Device Name: Zavation Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: May 25, 2021
Received: May 26, 2021

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,

for

Colin O'Neill, M.B.E.
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)*
211113

Device Name

Zavation Spinal System

Indications for Use *(Describe)*

The Zavation Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Zavation Spinal Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Zavation Spinal Systems when used as anterior thoracic/lumbar screw fixation systems, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

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.

510K Summary

Date:	July 9, 2021
Submitter:	Zavation Medical Products, LLC 220 Lakeland Parkway Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Katie Motley
Type of 510(k) submission:	Traditional
Trade name:	Zavation Spinal System
Common name:	Spinal Fixation System
Classification regulation:	Thoracolumbosacral Pedicle Screw System, 21 CFR 888.3070 (NKB) Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060 (KWQ)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	NKB, KWQ
Basis for submission:	Addition of components

Purpose: The purpose of this submission is to request clearance for HA coated Zavation Spinal System implants.

Device Description: The Zavation Spinal System is comprised of polyaxial pedicle screws, rods, and cross connectors. The Zavation Spinal System can be used for single or multiple level fixations. The standard pedicle screws have various options in lengths and diameters as well as a sterile packaged Hydroxyapatite (HA) coated option. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors.

Indications for Use:
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Materials:
The Zavation Spinal System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 and cobalt chrome alloy (Co-28Cr-6Mo) as described by ASTM F1537. The Hydroxyapatite (HA) coating is applied in compliance with ASTM F1185, ASTM F1044, & ASTM F1147

Predicate Devices:
Primary predicate: K190317 Zavation Spinal System [Zavation]
Additional predicate: K180179 Firebird Spinal Fixation System [Orthofix]

Performance Data:
Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case construct. The mechanical test results demonstrated substantial equivalency to the predicate device.

Comparison of Technological Characteristics:
The Zavation Spinal System possesses the same technological characteristics as the predicate devices. These include: basic design (rod based fixation system having polyaxial pedicle screws with various screw and rod diameters and lengths), material (titanium alloy), mechanical safety and performances, and intended use (as described above).

Substantial Equivalence Conclusion:
The Zavation Spinal 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.