DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 21, 2016

Zavation, LLC
Mr. Lawrence Walker
Engineering Manager
400 Liberty Park Drive
Flowood, Mississippi 39232

Re: K153404
Trade/Device Name: Zavation Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWQ
Dated: March 23, 2016
Received: March 24, 2016

Dear Mr. Walker:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

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

Enclosure

Indications for Use

510(k) Number: K153404

Device Name: Zavation Spinal System

Indications For Use:

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).

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510K Summary

Date:	April 19, 2016
Submitter:	Zavation LLC 400 Liberty Park Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Lawrence Walker
Type of 510(k) submission:	Traditional
Trade name:	Zavation Spinal System
Common name:	Spinal Fixation System
Classification regulation:	888.3070 (MNH, MNI) 888.3060 (KWQ)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	MNH, MNI, KWQ
Basis for submission:	Addition of components

Purpose: The purpose of this submission is to request clearance for additional Zavation Spinal System implants and instruments.

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 pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors.

Intended Use:
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).

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Materials:
The Zavation Spinal System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Devices:
Zavation Spinal System (K112484) -primary
Depuy Spine Moss Miami Spine System (K955348)
U&I Corporation OPTIMA Spinal System (K024096)
Depuy Synergy VLS open (K000236)
Synthes Matrix System (K120838)

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 that the Zavation Spinal System performs as well as or better than the predicate devices.

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).

Basis for Substantial Equivalence:
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.