March 18, 2019

Zavation Medical Products LLC
Matt Jones
Design Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

Re: K190361
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: February 13, 2019
Received: February 15, 2019

Dear Matt Jones:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190361

Device Name
Zavation Spinal System

Indications for Use *(Describe)*
The Zavation Spinal System is 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 thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

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:	March 18, 2019
Submitter:	Zavation Medical Products LLC 220 Lakeland Pkwy Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact Person:	Matt Jones
Type of 510(k) submission:	Traditional
Trade name:	Zavation Spinal System
Common name:	Spinal Fixation System
Classification regulation:	888.3070 (NKB) 888.3060 (KWQ)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	NKB, KWQ
Basis for submission:	Addition of new components
Prior Submissions:	K112484 and K153404. Both received Substantial Equivalence determinations

Device Description:
The Zavation Spinal System is comprised of polyaxial pedicle screws, rods, and rod 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, offsets, and connectors.

Intended Use:

The Zavation Spinal System is 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 thoracic, lumbar, and sacral spine; degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

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.

Primary Predicate Device:
K153404 Zavation Spinal System [Zavation]

Reference Devices:
K180179 Firebird Spinal Fixation System [Orthofix]
K132126 Zavation Fenestrated Facet Screw System [Zavation]

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).

Performance Data:
Biomechanical testing including static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case construct. Axial and torsional grip of rod connectors was tested according to ASTM F1798. The mechanical test results demonstrated that the Zavation Spinal System performs as well as or better than the predicate devices.

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.