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

Zavation, LLC
Mr. Frankie Cummins
Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

March 22, 2016

Re: K160362
Trade/Device Name: Z-Span Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 8, 2016
Received: February 9, 2016

Dear Mr. 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. 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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160362

Device Name
Z-Span Plate System

Indications for Use *(Describe)*
The Z-Span Plate System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the lumbar spine (L1-L5) or via the anterior approach below the bifurcation of the great vessels in the treatment of the lumbar and lumbosacral spine (L1-S1).
The Z-Span Plate System is intended to provide immobilization and stabilization as an adjunct to fusion in skeletally mature patients in the treatment of the following:
• Fracture (including dislocation and subluxation)
• Tumor
• Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
• Pseudoarthrosis
• Spondylolysis
• Spondylolisthesis
• Scoliosis
• Lordotic deformities of the spine
• Spinal stenosis
• Failed previous spine surgery

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:	Feb 08, 2016
Submitter:	Zavation, LLC 220 Lakeland Parkway Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Frankie Cummins
Type of 510(k) submission:	Traditional
Trade name:	Z-Span Plate System
Common Name:	Spinal Fixation System
Classification regulation/code:	888.3060, KWQ
Classification name:	Spinal Intervertebral Body Fixation Orthosis
Device classification:	Class II
Classification Panel:	Orthopedic
Basis for submission:	New device

Device Description:
The Z-Span Plate System is supplemental fixation device consisting of a variety of shapes and sizes of one-level lumbar and sacral plates and screws. The plates attach to the lumbar and lumbosacral spine (L1-S1). The implant components are made of titanium alloy per ASTM F-136 (Ti-6AL-4V ELi)

Indications for Use:
The Z-Span Plate System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the lumbar spine (L1-L5) or via the anterior approach below the bifurcation of the great vessels in the treatment of the lumbar and lumbosacral spine (L1-S1).

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- Fracture (including dislocation and subluxation)
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- Pseudoarthrosis
- Spondylolysis
- Spondylolisthesis
- Scoliosis
- Lordotic deformities of the spine
- Spinal stenosis
- Failed previous spine surgery

Predicate Device:
Primary: Synthes, Antegra System (K063158)
Additional: Orthofix, Skyhawk Plate System (K140260)

Technological Characteristics:
The technological characteristics including material, design and performance of the Z-Span Plate System are consistent with those of the predicate devices.

Performance Data:
Mechanical testing of the Z-Span Plate System consisting of static and dynamic axial compression bending testing and static torsion testing was conducted in accordance with ASTM F1717. Test results demonstrate that the Z-Span Plate System performs as well as or better than the predicate device and is therefore substantially equivalent to the predicate devices.

Conclusion:
Based on the similarities in materials, design, principles of function, intended use and indications, the Z-Span Plate system has been shown to be substantially equivalent to the predicate devices. Non-clinical data demonstrates the Z-Span Plate System is as safe, as effective, and performs as well as the predicate devices. The Z-Span Plate System does not raise new safety and effectiveness questions.