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. Milton Phillips
Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

October 20, 2016

Re: K161016
Trade/Device Name: Z-Clamp ISP System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 20, 2016
Received: September 21, 2016

Dear Mr. Phillips:

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" (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 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,

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)*
K161016

Device Name
Z-Clamp ISP System

Indications for Use *(Describe)*
The Z-Clamp ISP System is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous process for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease – 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) and/or tumor. The Z-Clamp ISP System is not intended for standalone use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K Summary

Date:	September 20, 2016
Submitter:	Zavation, LLC 220 Lakeland Parkway Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Milton Phillips
Trade name:	Z-CLAMP ISP System
Classification:	Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050 Product Code: PEK Regulatory Class: II Panel Code: 87
Primary Predicate:	K141508 Spineart, Romeo 2Pad

Device Description:
The Zavation Z-CLAMP ISP System is a spinous process plate which is a temporary, titanium alloy (Ti-6AL-4V ELI per ASTM F136), multiple component system comprised of a variety of non-sterile, single use implantable components. The system consist of plates and lock screw. The components are available in a variety of lengths and sizes in order to accommodate patient anatomy.

Indications for Use:
The Z-Clamp ISP System is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous process for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease – 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) and /or tumor. The Z-Clamp ISP System is not intended for standalone use.

Technological Characteristics:
The Z-CLAMP ISP System possesses the same technological characteristics, design and principles of operation as the predicates. These include: basic design, material, intended use and indications.

Performance Data:
Static torsion test, static compression bending test, dynamic compression bending test, static foam pull-off test and static plate dissociation test were performed according to a modified ASTM F1717 on a worst-case construct. The mechanical test results demonstrated the Z-CLAMP ISP System performs as well as or better than the predicate devices.

Conclusion:
The Z-CLAMP ISP System is substantially equivalent to the predicate device referenced above.