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 3, 2017

Re: K162575
Trade/Device Name: Z-LINK$_{PC}$ System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: February 6, 2017
Received: February 7, 2017

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 Part 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)*
K162575

Device Name
Z-LINKPC System

Indications for Use *(Describe)*
The Z-LINKPC System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Z-LINKPC System may be connected to the Zavation Spinal System using rod connectors and tapered rods.

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 2, 2017
Submitter:	Zavation, LLC 220 Lakeland Parkway Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Frankie Cummins
Trade name:	Z-LINK$_{PC}$ System
Classification:	Cervical Pedicle Spinal Fixation Orthosis Product Code: NKG Regulatory Class: Unclassified, Pre-Amendment Per 21 CFR as follows: 888.3050 Spinal Interlaminal Fixation Orthosis Product Code: KWP Regulatory Class: II, Panel Code: 87
Predicates:	Primary: K142838 Synthes, Synapse System Additional: K122378 Biomet, Altius System

Device Description:
The Z-LINK$_{PC}$ System 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 polyaxial screws, hooks, rods, cross-connectors, rod connectors, offsets and cap screws. The components are available in a variety of lengths and sizes in order to accommodate patient anatomy.

Intended Use:
The Z-LINK$_{PC}$ System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by

radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Z-LINKPC System may be connected to the Zavation Spinal System using rod connectors and tapered rods.

Technological Characteristics:
The Z-LINK$_{PC}$ 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 axial compression bending and torsion, and dynamic axial compression bending test were performed according to ASTM F1717 on a worst-case construct. Axial and torsional grip test were performed according to ASTM F1798 on the connectors. The mechanical test results demonstrated the Z-LINK$_{PC}$ system performs as well as or better than the predicate devices.

Conclusion:
The Z-LINK$_{PC}$ system is substantially equivalent to the predicate device referenced above.
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