August 11, 2021

Zavation Medical Products LLC
Colby Williams
Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

Re: K211993
Trade/Device Name: Z-LINK$_{PC}$ System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 25, 2021
Received: June 28, 2021

Dear Colby Williams:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K211993

Device Name
Z-LINK$_{PC}$ System

Indications for Use *(Describe)*

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.

To achieve additional levels of fixation, the Z-LINK$_{PC}$ System may be connected to the Zavation Spinal System using rod connectors and tapered rods.

When used with the occipital plate, the Z-LINK$_{PC}$ System is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic juction (occiput-T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

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:	June 25, 2021
Submitter:	Zavation Medical Products LLC 220 Lakeland Pkwy Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact Person:	Colby Williams
Type of 510(k) submission:	Traditional
Trade name:	Z-LINK$_{PC}$ System
Classification regulation:	21 CFR 888.3075 Posterior Cervical Screw System 21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis
Device classification:	Class II
Classification Panel:	Orthopedic Devices
Product code:	NKG, KWP
Basis for submission:	Addition of occipital plate.

Device Description:
The Z-LINK$_{PC}$ System is a temporary, titanium alloy (Ti-6AL-4V ELI per ASTM F136) and cobalt chrome alloy (Co-28Cr-6Mo per ASTM F1537), 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, occipital plates, bone screws, and cap screws. The components are available in a variety of lengths and sizes in order to accommodate patient anatomy.

Indications for 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.

To achieve additional levels of fixation, the Z-LINK$_{PC}$ System may be connected to the Zavation Spinal System using rod connectors and tapered rods.

When used with the Occipital Plate, the Z-LINK$_{PC}$ System is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic junction (occiput-T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

Materials:
The Z-LINK$_{PC}$ System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136, and cobalt chromium alloy (Co-28Cr-6Mo) as described by ASTM F1537.

Primary Predicate Device:
K180198 Nuvasive Viewpoint

Additional Predicate Device:
K180025 Orthofix Centurion

Technological Characteristics:
The Z-LINK$_{PC}$ system possesses the same technological characteristics as the predicate devices. These include basic design (rod based fixation system having occipital bone screws and various accessories), material (titanium alloy/cobalt chrome alloy), mechanical safety and performance, and intended use.

Performance Data:
Static compression bending and torsion, dynamic compression bending, and dynamic torsion tests were performed according to ASTM F2706 on a worst-case construct. 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 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 to the predicate devices.