Zavation Medical Products, LLC
Noah Slack
Engineer
3670 Flowood Dr.
Flowood, Mississippi 39232

August 22, 2023

Re: K231811
Trade/Device Name: Zavation Connector System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, NKG, KWP
Dated: June 16, 2023
Received: June 21, 2023

Dear Noah Slack:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.08.22 10:10:03 -04'00'

for

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)*
K231811

Device Name
Zavation Connector System

Indications for Use *(Describe)*
When used with the Zavation ZLinkPC System for Posterior-Cervical-Thoracic (Occ-T3)

The Zavation Connector 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 of the craniocervical junction, the cervical spine (C1 to 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.

When used with the Zavation Spinal System for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Illium)

The Zavation Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Illium) in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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:	June 16, 2023
Submitter:	Zavation Medical Products, LLC 3670 Flowood Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Noah Slack
Type of 510(k) submission:	Traditional
Trade name:	Zavation Connector System
Common name:	Connector System
Classification regulation:	Thoracolumbosacral Pedicle Screw System, 21 CFR 888.3070 (NKB) Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060 (KWQ) Posterior Cervical Screw System, 21 CFR 888.3075 (NKG) Appliance, Fixation, Spinal Interlaminal, 21 CFR 888.3050 (KWP)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	NKG, KWP, NKB, KWQ
Basis for submission:	New Device

Purpose: The purpose of this submission is to request clearance for Zavation Connector System instruments and implants.

Device Description: The Connector System is designed to aid in revision surgeries and extensions of existing hardware constructs from the Occiput to the Ilium. The Connector System includes a variety of non-sterile titanium implants including parallel rod to rod domino connectors, axial connectors with and without attachment rods, bypass connectors, lateral offsets, double tulips (angled and parallel), and Z rods. The implant options allow revisions and extension to be performed without removing existing hardware. The Zavation Connector System is designed to be used with the Zavation Z-Link$_{PC}$ System for Posterior-Cervical-Thoracic (Occ-T3) and the Zavation Spinal System for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Illium).

Indications for Use:
When used with the Zavation ZLinkPC System for Posterior-Cervical-Thoracic (Occ-T3)

The Zavation Connector 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 of the craniocervical junction, the cervical spine (C1 to 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.

When used with the Zavation Spinal System for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Illium)

The Zavation Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Illium) in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Materials:
The Zavation Connector System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Primary Predicate Device:
K170647 Connector System [Orthofix]

Additional Predicate Devices:
K222614 Zavation Modular System [Zavation]
K112484 Zavation Spinal System [Zavation]
K162575 Zavation Z-Link$_{PC}$ System [Zavation]

Performance Data:
Static axial and torsional grip were performed according to ASTM F1798 on a worst-case construct. The mechanical test results demonstrated substantial equivalency to the predicate device.

Comparison of Technological Characteristics:
The Zavation Connector System possesses the same technological characteristics as the predicate devices. These include: basic design and dimensions, material (titanium alloy), mechanical safety and performances, and intended use (as described above).

Substantial Equivalence Conclusion:
The Zavation Connector 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.