August 12, 2022

Zavation Medical Products, LLC
Katie Motley
Design Engineer
3670 Flowood Drive
Flowood, Mississippi 39232

Re: K221049
Trade/Device Name: Zavation VariSync Plate System & VariSync Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device With Integrated Fixation, Cervical
Regulatory Class: Class II
Product Code: OVE, ODP, KWQ
Dated: July 15, 2022
Received: July 19, 2022

Dear Katie Motley:

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,

Brent Showalter, Ph.D.
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)*
K221049

Device
VariSync Plate System & VariSync Spacer System

Indications for Use *(Describe)*
The VariSync Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The VariSync Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The VariSync Spacer is to be filled with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. These devices are intended to be used with supplemental fixation such as the Zavation VariSync Plate, Zavation Midline Plate, Zavation EZ Plate, or Zavation Cervical Plate Systems. When used with the VariSync Plate, the assembly takes on the indications of the VariSync Spacer, with the VariSync Plate acting as the supplemental fixation.

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:	April 6, 2022
Submitter:	Zavation Medical Products, LLC 3670 Flowood Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Katie Motley
Type of 510(k) submission:	Traditional
Trade name:	VariSync Plate System And VariSync Spacer System
Common name:	Intervertebral Body Fusion Device
Classification regulation:	21 CFR 888.3080 Intervertebral body fusion device
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	OVE, ODP, KWQ
Basis for submission:	New Device

Device Description:

The VariSync Plate is an anterior, cervical fixation device available in various heights and widths to fit the anatomical needs of a wide variety of patients. The plates are made from titanium alloy, as specified in ASTM F136. The Screws for use with the VariSync Plates are manufactured from titanium alloy, as specified in ASTM F136.

VariSync Spacers are anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and footprints to fit the anatomical needs of a wide variety of patients. These devices are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. The VariSync Spacers are manufactured from radiolucent PEEK polymer, with tantalum markers, as specified in ASTM F2026 and F560.

Intended Use:
The VariSync Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The VariSync Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The VariSync Spacer is to be filled with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. These devices are intended to be used with supplemental fixation such as the Zavation VariSync Plate, Zavation Midline Plate, Zavation EZ Plate, or Zavation Cervical Plate Systems. When used with the VariSync Plate, the assembly takes on the indications of the VariSync Spacer, with the VariSync Plate acting as the supplemental fixation.

Materials:
The spacer is manufactured from medical grade PEEK Zeniva ZA-500 or Superior Polymers Magnolia PEEK (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

Predicate Device:
Primary -Zavation IBF System, Zavation LLC (K202305)
Primary – Zavation Cervical Plate System (181244)
Additional – Globus COALITION AGX (K142218)
Additional – Elevation Spine Saber-C (K190885)
Additional – Zavation Ti3Z Cervical Interbody System (K202398)

Technological Characteristics:
The Zavation VariSync Plate and the Zavation VariSync Spacer possesses the same technological characteristics as the predicates. These include similar heights, widths, lengths, fixation method and intended use.

Performance Data:
Mechanical test results demonstrated that the Zavation VariSync Plate System and The VariSync Spacer System is substantially equivalent to the predicate devices. Testing for VariSync Spacer was performed in accordance with ASTM F2077, Test Methods for Intervertebral Body Fusion

Devices and ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression. Testing for VariSync Plate was performed in accordance with ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebral Model.

Basis for Substantial Equivalence:

The Zavation VariSync Plate System and VariSync Spacer 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 spacers to the predicate devices and is therefore as safe, as effective and performs as well as or better than the legally marketed device for its intended use.