



April 10, 2024

Zavation Medical Products LLC
Colby Williams
Design Engineer 2
3670 Flowood Drive
Flowood, Mississippi 39232

Re: K233509

Trade/Device Name: Zavation IBF System, Zavation Varisync Plate System and Varisync Spacer System, LABYRINTH System, Zavation ALIF System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX, ODP, OVE, KWQ, OVD

Dated: March 25, 2024

Received: March 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)
K233509

Device Name
Zavation IBF System

Indications for Use (Describe)

When used as a cervical intervertebral body fusion device, the Zavation IBF implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Zavation IBF implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. For all the above indications the Zavation IBF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

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)

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Indications for Use

510(k) Number (if known)

K233509

Device Name

VariSync Plate and 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 Zvation VariSync Plate, Zvation Midline Plate, Zvation EZ Plate, or Zvation 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)

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Indications for Use

510(k) Number (if known)
K233509

Device Name
LABYRINTH System

Indications for Use (Describe)

When used as a cervical intervertebral body fusion device, the LABYRINTH implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the LABYRINTH implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. For all the above indications the LABYRINTH implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

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)

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Indications for Use

510(k) Number (if known)
K233509

Device Name
Zavation ALIF System

Indications for Use (Describe)

The Zavation ALIF System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation ALIF System is to be filled with autogenous bone graft material.

The Zavation ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar spine.

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)

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510K Summary

Date:	April 3, 2024
Submitter:	Zavation Medical Products LLC 3670 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(s):	Zavation IBF System Zavation Varisync Plate System and Varisync Spacer System LABYRINTH System Zavation ALIF System
Common Name(s):	Intervertebral Fusion Device with Bone Graft, Cervical Intervertebral Fusion Device with Bone Graft, Lumbar Intervertebral Fusion Device with Integrated Fixation, Cervical Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification Regulation(s):	21 CFR 888.3080 Intervertebral body fusion device
Device Classification:	Class II
Classification Panel:	Orthopedic
Product Code(s):	MAX, ODP, OVE, KWQ, OVD
Basis for submission:	Addition of ion beam assisted deposition (IBAD) Titanium coating on PEEK interbody devices

Device Description:

The Zavation IBF implants offers a variety of heights, widths, and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone) Superior Polymers Magnolia PEEK (ASTM F2026).

The Zavation IBF implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. This modification seeks clearance for the addition of an ion beam assisted deposition (IBAD) coating made from Grade 2 Commercially Pure Titanium that meets chemical

composition requirements of ASTM F67 on previously cleared PEEK devices. The (IBAD) coated PEEK implants will be provided non-sterile.

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 Superior Polymers Magnolia PEEK, with tantalum markers, as specified in ASTM F2026 and F560. This modification seeks clearance for the addition of an ion beam assisted deposition (IBAD) coating made from Grade 2 Commercially Pure Titanium that meets chemical composition requirements of ASTM F67 on previously cleared PEEK devices. The (IBAD) coated PEEK implants will be provided non-sterile.

The LABYRINTH implants offer a variety of heights, widths and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone) Superior Polymers Magnolia PEEK (ASTM F2026).

The LABYRINTH implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The LABYRINTH device has a porous structure on the end plate and through the device. This modification seeks clearance for the addition of an ion beam assisted deposition (IBAD) coating made from Grade 2 Commercially Pure Titanium that meets chemical composition requirements of ASTM F67 on previously cleared PEEK devices. The (IBAD) coated PEEK implants will be provided sterile.

The Zavation ALIF System includes a spacer, plate, screws, and anchors. The spacer component is assembled to an interbody plate and implanted anteriorly. The spacer components are available in a variety of materials, depths, widths, and heights. The plate component includes three or four holes for inserting bone screws or anchors. The plate component also includes a lock at each hole. The bone screws are available in a variety of diameters and lengths. The anchors are available in a variety of lengths. The interbody plate components are available in a variety of heights. This modification seeks clearance for the addition of an ion beam assisted deposition (IBAD) coating made from Grade 2 Commercially Pure Titanium that meets chemical composition requirements of ASTM F67 on previously cleared PEEK devices. The (IBAD) coated PEEK implants will be provided non-sterile.

Intended Use:**Zavation IBF System**

When used as a cervical intervertebral body fusion device, the Zavation IBF implants is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Zavation IBF implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation IBF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Zavation Varisync Plate and Varisync Spacer System

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 is 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.

LABYRINTH System

When used as a cervical intervertebral body fusion device, the LABYRINTH implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the LABYRINTH implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the LABYRINTH implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Zavation ALIF System

The Zavation ALIF System is an anterior interbody fusion device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation ALIF System is to be filled with autogenous bone graft material.

The Zavation ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar spine.

Materials:

The devices are manufactured from medical grade PEEK Magnolia PEEK (ASTM F2026), or Titanium (ASTM F136) with Tantalum alloy position markers (ASTM F560). The PEEK implants are available with or without titanium plasma coating on the device, or an ion beam assisted deposition (IBAD) coating. The plasma coating is made from commercially pure titanium per (ASTM F1580). The (IBAD) coating is made from Grade 2 Commercially Pure Titanium coating that meets chemical composition requirements of (ASTM F67).

Primary Predicate Device:

K201367 FlareHawk Interbody Fusion System [Integrity Implants Inc.]

Additional Predicate Device:

K200084 Zavation IBF System [Zavation]

K221049 Zavation Varisync Plate System and Varisync Spacer System [Zavation]

K211306 LABYRINTH System [Zavation]

K230731 Zavation ALIF System [Zavation]

Technological Characteristics:

The subject device is identical in indications for use, surgical technique, instrumentation, and technological characteristics to the cleared additional predicate devices. The purpose of this submission is to include addition of an ion beam deposition (IBAD) coating made from Grade 2 Commercially Pure Titanium that meets the chemical composition requirements per (ASTM F67). The specifications of the titanium coating are identical to that of the primary predicate device cleared in (K201367).

Performance Data:

For this submission, coating properties were evaluated using standards ASTM F1147, ASTM F1044, ASTM F1160, and ASTM F1978. The following properties were tested:

- Tensile Bond Strength
- Static Shear Strength
- Shear Fatigue Strength
- Tabor Abrasion Test

Additional information on the (IBAD) coating can be found in the Master Access File of the coating vendor, N2 Biomedical.

Conclusion:

Based on bench performance testing, biocompatibility assessment, and other supporting documentation provided in this premarket notification the subject devices demonstrate

substantial equivalence to the cited legally marketed predicate devices, and any differences between the subject devices and predicate devices do not impact the safety and effectiveness of subject devices.