



June 24, 2021

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

Re: K211306
Trade/Device Name: LABYRINTH
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: April 28, 2021
Received: April 29, 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,

Brent L. 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)

K211306

Device Name

LABYRINTH

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)

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
PRASStaff@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: April 28, 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: LABYRINTH

Intervertebral Body Fusion Device: Intervertebral Body Fusion Device

Classification regulation: 21 CFR 888.3080 Intervertebral body fusion device

Device classification: Class II

Classification Panel: Orthopedic

Product code: MAX, ODP

Basis for submission: New porous device

Device Description:

The LABYRINTH 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).

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 includes a porous structure on the endplate and through the device. This submittal seeks clearance for LABYRINTH implants. The implants will be provided sterile.

Intended Use:

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.

Materials:

The devices are manufactured from medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum alloy position markers (ASTM F560) or titanium per (ASTM F136).

Primary Predicate Device:

K202305 Zavation IBF System [Zavation]

Technological Characteristics:

The subject device is identical in indications for use, surgical technique, and instrumentation to the primary predicate device cleared in (K202305). The LABYRINTH device includes a porous structure on the endplate and through the device. LABYRINTH device possesses the same technological characteristics as the primary predicate. These include similar heights, widths, lengths, and intended use.

Performance Data:

Biomechanical test results demonstrated that the LABYRINTH System is substantially equivalent to the predicate devices. Testing was performed in accordance with:

- ASTM F2077, Test Methods for Intervertebral Body Fusion Devices
 - Static Axial Compression
 - Dynamic Axial Compression
 - Static Torsion

- ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- Static Pushout Test Method for Intervertebral Body Fusion Devices.

Conclusion:

The LABYRINTH 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.