October 19, 2020

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

Re: K200084
Trade/Device Name: Zavation IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: September 17, 2020
Received: September 18, 2020

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,

for
Brent Showalter, Ph.D.
Acting 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)*
K200084

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K Summary

Date:	September 17, 2020
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:	Zavation IBF System
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:	Addition of titanium coated implants.

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).

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 PEEK devices coated with a plasma-spray Titanium coating. The Titanium coated implants will be provided non-sterile.

Intended Use:
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.

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). The implants are available with or without titanium plasma coating on the device. The plasma coating is made from commercially pure titanium per (ASTM F1580).

Primary Predicate Device:
K181246 Zavation IBF System [Zavation]

Additional Predicate Device:
K150061 Lucent Ti-Bond® [Spinal Elements]

Additional References:
K180076 Zavation Ti-3Z IBF System TLIF [Zavation]
K122097 Globus Medical Continental™ ALIF System A Patriot™ Spacer 20x25mm [Globus]
K180076 Zavation Ti-3Z IBF System CIF 12x14 [Zavation]

Technological Characteristics:
The subject device is similar in indications for use, surgical technique, and instrumentation to the primary predicate device cleared in (K181246). The difference to the Zavation IBF System is the addition of a titanium coated surface. The specifications of the titanium coating are identical to that of the additional predicate device cleared in (K150061). Zavation IBF System possesses the same technological characteristics as the predicates. These include similar heights, widths, lengths, and intended use.

Performance Data:
Zavation Medical Products has previously submitted to the FDA results of performance testing for Zavation IBF System implants:

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

Coating properties were evaluated using standards ASTM F1147, ASTM F1044, ASTM F1160, ASTM F1854, and ASTM F1978. The following properties were tested:

- Tensile Bond Strength
- Shear Fatigue Strength
- Static Shear Strength
- Abrasion Test
- Metallurgical Testing and Image Analysis of coated surface

Additional information on the titanium coating can be found in the Master Access File of the coating vendor, APS Materials.

Therefore, no additional testing was performed for the purpose of this submission.

Conclusion:
The Zavation IBF 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.