March 27, 2018

Zavation Medical Products LLC
Matt Jones
Design Engineer
220 Lakeland Parkway
Flowood, Mississippi 39232

Re: K180537
Trade/Device Name: Zavation Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 27, 2018
Received: February 28, 2018

Dear Matt Jones:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180537

Device Name
Zavation Buttress Plate System

Indications for Use *(Describe)*
The Zavation Buttress Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

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:	February 27, 2018
Submitter:	Zavation Medical Products LLC 220 Lakeland Pkwy Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact Person:	Matt Jones
Type of 510(k) submission:	Traditional
Trade name:	Zavation Buttress Plate System
Common name:	Anterior Buttress Plate
Classification regulation:	888.3060
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	KWQ

Device Description:
The Zavation Buttress Plate System consists of screws and plates. Screws are available in a variety of diameter and length combinations. Plates are available in a variety of lengths.

Intended Use:
The Zavation Buttress Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

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

Primary Predicate Device:
K081770 Black Widow Anterior Buttress Plate System [Spinal Elements]

Additional Predicate Devices:
K061482 Altes Anterior Buttress Plating System [Exactech Spine]
K112533 Zavation Cervical Plate System [Zavation]

Technological Characteristics:
The Zavation Buttress Plate System possesses the same technological characteristics as the predicates. These include: basic design (plate designed system having various screw diameters and lengths), material (titanium alloy), sizes (variety of plate and screw sizes), and intended use (as described above).

Performance Data:
Biomechanical testing, including static and fatigue cantilever beam loading were conducted.

Conclusion:
The Zavation Buttress Plate System is substantially equivalent to the devices referenced above.