January 22, 2018

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

Re: K173306
Trade/Device Name: EZ Plate™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 18, 2017
Received: December 19, 2017

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,

Vincent J. Devlin -S

for

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)*
K173306

Device Name
EZ Plate™

Indications for Use *(Describe)*
The EZ Plate™ cervical plate system is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

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:	December 18, 2017
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:	EZ Plate™
Common name:	Anterior Cervical Plate
Classification regulation:	888.3060
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	KWQ

Device Description:
The EZ Plate™ cervical plate system consists of self-tapping/self-drilling 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 EZ Plate™ cervical plate system is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Materials:
The EZ Plate™ cervical plate system components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Primary Predicate Device:
K112533 Zavation Cervical Plate System

Additional Predicate Devices:
K133518 Biomet MaxAn
K021761 Medtronic Premier Plate
K001794 EBI Cervical Plate System

Technological Characteristics:
The EZ Plate™ cervical plate system possesses the same technological characteristics as the predicate. These include: basic design (plate designed fixation 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:
Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. The mechanical test results demonstrated that the EZ Plate™ cervical plate system performs as well as or better than the predicate devices.

Conclusion:
The EZ Plate™ cervical plate system is substantially equivalent to the devices referenced above and is therefore safe and effective for its intended use.