DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2015

Z-Medical GmbH & Company KG
Mr. Alexander Henninger
Quality Manager
Gansacker 38
78532 Tuttlingen
GERMANY

Re: K143200
Trade/Device Name: MIS Z-Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: November 1, 2014
Received: November 6, 2014

Dear Mr. Henninger:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143200

Device Name
MIS Z-Pedicle Screw System

Indications for Use *(Describe)*
The MIS Z-Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications:
- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis (grades 3 and 4) at L5-S1
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- curvatures (i.e.,scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- 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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"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."

K143200

510(k) Summary

DATE OF PREPARATION: 2015-02-02

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1. Device Name

1.1. MIS Z-Pedicle Screw System

Trade Names: MIS Z-Pedicle Screw System
Common Name: Pedicle Screw System
Classification Name: Pedicle screw spinal System

2. Classification Product Code / Subsequent Code

2.1. MIS Z-Pedicle Screw System

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number	Classification name
Pedicle screw spinal fixation	Part 888	Orthopedic	NKB, MNI, MNH	III	888.3070	Pedicle Screw Spinal System

3. Predicate Device

Z-Medical's MIS Pedicle Screw System is substantially equivalent to the following predicate devices, most recently cleared by the FDA:

Z-Medical Product	Primary Predicate Device	510(k) Number	510(k) Holder
MIS Z- Pedicle Screw System	CD HORIZON	K031655	Medtronic
	Additional Predicate Device	**510(k) Number**	**510(k) Holder**
	VIPER 2	K090648	DePuy Spine
	EXPEDIUM / VIPER / VIPER 2	K131802	DePuy Spine

4. Description of the Device

4.1. MIS Z-Pedicle Screw System

The MIS Z- Pedicle Screw System consists of a variety of Pedicle screws and rods in different sizes. The devices are intended to provide immobilization and stabilization of the spinal segments for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion.

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g. osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Z-Pedicle Screws:
Material: ASTM F136 (Ti-6Al-4V ELI)
Length: 35mm to 55 mm
Diameter: 5, 6, 7, 8 mm

Z- Rods:
Material: ASTM F136 (Ti-6Al-4V ELI)
Length: 35mm to 300mm
Diameter: 5,5 mm

5. Indications for Use

5.1. MIS Z- Pedicle Screw System

The MIS Z-Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis (grades 3 and 4) at L5-S1
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- curvatures (i.e.,scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion.

6. Testing

The following testing was done to show safety and effectiveness of our system:

1. biocompatibility

Materials that come into contact with the patient were identified as well as products that might contaminate the implants and instruments during manufacturing processes. Materials are listed and viewed, testing according EN ISO 10993-5

2. sterilization

Microbiological performance qualification of gamma radiation sterilization (basic qualification, method VDmax25) was performed according EN ISO 11137-1 and showed that the products are sterile with SAL of 10^6

3. packaging / shelf life

Shelf life of packaging was performed by Puracon with a packaging validation. With the PA/PE bags we use, we're superior to the worst case product

4. bench testing - mechanical

Testing in order to help establish safety and effectiveness of Z-Medical's MIS Pedicle Screw System has been performed accordingly and results are conforming to the respective requirements.

Mechanical tests:

- ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
  The following testing was performed:

  - static compression bending
  - static tension bending
  - static torsion
  - dynamic compression bending
- ASTM F1798 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
  The following testing was performed: static gripping capacity

Result: the results of the testing exceed the values we defined in our rational for the worst case scenario based on literature.

7. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Z-Medical's MIS Pedicle Screw System is considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.