DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Biedermann Motech GmbH & Co. KG
Mr. Gerd Federle
Director of Quality Management
Bertha-von-Suttner-Str. 23
78054 Villingen-Schwenningen
GERMANY

Re: K170890
Trade/Device Name: TELIX K Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 24, 2017
Received: March 27, 2017

Dear Mr. Federle:

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,

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)*
K170890

Device Name
TELIX K Interbody System

Indications for Use *(Describe)*
The TELIX K Interbody System is indicated for use as intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1).
Patients should have six months of non-operative treatment prior to surgery.
These implants are used to facilitate fusion in the lumbar spine and are placed via a TLIF approach using autogenous bone.
These implants are intended for use with Biedermann Motech supplemental internal fixation products.

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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510(k) Summary

1. Submitter, Correspondent and Manufacturer

Submitter Name: Biedermann Motech GmbH & Co. KG

Submitter Address: Bertha-von-Suttner-Str. 23
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Germany

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Date of Submission: 03/24/2017

Manufacturer Name: Biedermann Motech GmbH & Co. KG

Manufacturer Address: Bertha-von-Suttner-Str. 23
78054 Villingen-Schwenningen
Germany

2. Device Identification

Device Trade Name: TELIX K Interbody System

Device Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification Name: Intervertebral Body Fusion with Bone Graft, Lumbar

Classification Code: MAX, Class II

Classification Panel: Orthopedic

Regulation Number: 21 CFR section 888.3080

Regulation Name: Intervertebral body fusion device

3. Predicate Device

Predicate Device:

- Depuy Spine Devex System - DePuy Spine, Inc (K081917)

Reference Devices:

- Aleutian IBF System – K2M, Inc. (K082698)
- MectaLIF – Medacta International (K110927)
- T-PAL Spacer System – Synthes USA Products LLC (K162358)

4. Device Description

The TELIX K Interbody System is intended for use as an intercorporal fusion cage in the lumbar region (L2-L5) and sacral region (S1). Therefore, the system includes the following implants:

The TELIX K Interbody System is comprised of slightly curved implants in lengths of 28, 32 and 36mm and heights ranging from 7 to 17mm.
Devices that are 7mm in thickness are only available with 0-degrees of lordosis and all other implants possess 5-degrees of lordosis.

The implants are introduced via a TLIF approach using autogenous bone.
The TELIX K Interbody System must only be implanted in combination with supplemental fixation.

The implants of the TELIX K Interbody System are single-use only and the system is provided non sterile.

5. Material

The implants are manufactured from ASTM F 136 implant grade titanium alloy Ti-6Al-4V ELI.

6. Indications for Use

The TELIX K Interbody System is indicated for use as intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1).
Patients should have six months of non-operative treatment prior to surgery.

These implants are used to facilitate fusion in the lumbar spine and are placed via a TLIF approach using autogenous bone.

These implants are intended for use with Biedermann Motech supplemental internal fixation products.

7. Technological Characteristics and Substantial Equivalence

Like the predicate device (DEVEX System – K081917) the TELIX K Interbody System consists of cages that are available in varying sizes to fit the patient's anatomical and physiological requirements.

The TELIX K cages are of a similar design and made from Titanium alloy Ti-6Al-4V, as the predicate is.

The System is intended to provide intervertebral body fusion in skeletally mature patients, as the predicate is.

8. Performance Data

8.1 Non-Clinical Test Summary

The TELIX K Interbody System was evaluated per the FDA Guidance Document for Industry and FDA Staff; Class II Special Controls Guidance Document Intervertebral Body Fusion Device.

The following testing was done to show substantial equivalence of our system:

Bench testing - mechanical

Mechanical testing according to ASTM F2077-14 (Test Methods for Intervertebral Body Fusion Devices) and ASTM F2267-04 standard (Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression) was performed in order to provide data to support a substantial equivalence determination. These tests were performed to support system related performance under consideration of well-established acceptance criteria. Performance testing included:

- Static Compression
- Dynamic Compression
- Static Torsion
- Static Compression-Shear
- Dynamic Compression-Shear
- Subsidence

Result: The results of the worst case biomechanical testing of the TELIX K Interbody System indicate that the system is substantially equivalent to the identified predicate/reference devices.

8.2 Clinical Test Summary

No clinical tests were performed.

9. Substantial Equivalence Summary and Conclusion

There are no differences between the devices which would raise new concerns regarding safety or effectiveness.
Based on available 510(k) information provided, comparison to predicate devices and performance testing, the TELIX K Interbody System can be considered substantially equivalent to the predicate/reference devices.