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

November 17, 2016

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

Re: K162232
Trade/Device Name: MOSS 100 Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: October 21, 2016
Received: October 24, 2016

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)*
K162232

Device Name
MOSS 100 Pedicle Screw System

Indications for Use *(Describe)*

The MOSS 100 Pedicle Screw System is a thoracolumbar pedicle fixation device for the following indications of use:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fractures or dislocations)
- Spinal Stenosis
- Curvatures (i.e. scoliosis, kyphoses 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

1. Submitter, Correspondent and Manufacturer

Submitter Name: Biedermann Motech GmbH & Co. KG

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

Contact Person: Gerd Federle
Director of Quality Management
Phone: +49 7720 8510-545
Fax: +49 7720 8510-66
gfe@biedermann.com

Date Prepared: 10/21/2016

Manufacturer Name: Biedermann Motech GmbH & Co. KG

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

2. Device Identification

Device Trade Name: MOSS 100 Pedicle Screw System

Device Common Name: Pedicle Screw System

Classification Name: Pedicle Screw Spinal fixation

Classification Code: NKB, MNI and MNH (Class III)

Classification Panel: Orthopedic

Regulation Number: 21 CFR section 888.3070

Regulation Name: Pedicle screw spinal system

3. Primary Predicate Device

K041119 Expedium Spine System, DePuy Spine, Inc.

4. Reference Device

K092929 Synthes Matrix Spine, Synthes (USA)

5. Device Description

The Biedermann Motech MOSS 100 Pedicle Screw System is a comprehensive thoracolumbar spinal system that offers posterior clinical solutions.
The MOSS 100 System is a universal set of instruments and implants that are indicated for the treatment of significant mechanical instability or deformity of the spine which requires fusion with instrumentation.

The MOSS 100 System provides several options for stabilization of the spine. Therefore, the system includes the following implants:

- Pedicle Screws Ø5-8mm, length 25-80mm
- Rods Ø5.5mm, length 30-95mm, 300mm and 480mm
- Locking caps
- Polyaxial Heads

The Polyaxial Heads are mounted onto the Pedicle Screws intra-operatively. The implants of the MOSS 100 System are single-use only and the system is provided non sterile.

6. Material

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

7. Indications for Use

The MOSS 100 Pedicle Screw System is a thoracolumbar pedicle fixation device for the following indications of use:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fractures or dislocations)
- Spinal Stenosis
- Curvatures (i.e. scoliosis, kyphosis and/ or lordosis)
- Tumor

- Pseudoarthrosis
- Failed previous fusion

8. Technological Characteristics and Substantial Equivalence

Like the predicate devices (Expedium Spine System – K041119, Synthes Matrix Spine – K092929) the MOSS 100 Pedicle Screw Systems is a multiple component device, made from Titanium alloy Ti-6Al-4V that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The MOSS 100 spinal implant assembly consists of pedicle screws, heads (interconnection mechanisms), locking caps and rods of a similar design as the predicate devices components.
The System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients, as the predicate is.

9. Performance Data

9.1 Non-Clinical Test Summary

The MOSS 100 system was evaluated per the FDA Guidance Document for Industry and FDA Staff; Spinal System 510(k)s.

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

Bench testing - mechanical
Mechanical testing according to ASTM F 1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model standard 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

Result: The results of the worst case mechanical testing of the MOSS 100 System indicate that the MOSS 100 system is substantially equivalent to the identified predicate device.

Additional Bench testing
Mechanical testing according to ASTM F 1798 (Standard Test Methods for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants) standard was performed in order to provide data to support a substantial equivalence determination. These

tests are performed to support system related performance under consideration of well-established acceptance criteria. Performance testing included:

- Static axial pull-off test

Results: Review and comparison of the data shows the subjects Biedermann Motech device has higher mechanical characteristics than the reference product. The test data supports substantial equivalence of performance of the Biedermann Motech subject device and reference product.

9.2 Clinical Test Summary

No clinical tests were performed.