August 20, 2021

Biedermann Motech GmbH & Co. KG
Gerd Federle
Director of Quality Management
Bertha-von Suttner-Strasse 23
Villingen-Schwenningen, Baden-Wuerttemberg 78054
Germany

Re: K203607
Trade/Device Name: MOSS VRS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: July 23, 2021
Received: July 26, 2021

Dear Gerd 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203607

Device Name
MOSS VRS Spinal System

Indications for Use *(Describe)*
The MOSS VRS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.
The MOSS VRS Spinal System is intended for posterior, non-cervical pedicle fixation for the following indications:
- degenerative disc disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.)
- spondylolisthesis
- trauma (i. e., fracture or dislocation)
- spinal stenosis
- curvatures (i. e., scoliosis, kyphosis and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the MOSS VRS System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The MOSS VRS System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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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K203607
510(k) Summary

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 of Submission:	07/23/2021
Manufacturer Name:	Biedermann Motech GmbH & Co. KG
Manufacturer Address:	Bertha-von-Suttner-Str. 23 78054 Villingen-Schwenningen Germany

Device Identification

Device Trade Name:	MOSS VRS Spinal System
Device Common Name:	Pedicle Screw Spinal System
Device Class:	Class II
Classification Name:	Thoracolumbosacral Pedicle Screw System, Spinal interlaminal fixation orthosis
Classification Code:	NKB, KWP
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3050
Regulation Name:	Thoracolumbosacral Pedicle Screw System, Spinal interlaminal fixation orthosis

Predicate Devices

Primary Predicate:	MOSS VRS Spinal System, Biedermann Motech GmbH & Co. KG (K181821)
Additional Predicates:	EXPEDIUM Spine System, DePuy Spine, Inc. (K131802)
	Nuvasive® GSB Global Spinal Balance System, Nuvasive Inc. (K132014)
	Nuvasive® Reline® System, Nuvasive Inc. (K160989)
	MOSS 100 Spinal System, Biedermann Motech GmbH & Co. KG (K162232)
	Synthes MATRIX System, Synthes Spine (K120838)
	Synthes Universal Spinal System, Synthes Spine (K990745)

Device Description

The Biedermann Motech MOSS VRS Spinal System is a comprehensive thoracolumbosacral spinal system that offers posterior clinical solutions and is indicated for the treatment of significant mechanical instability or deformity of the spine which requires fusion with instrumentation.

The MOSS VRS System consists of a variety of screws, polyaxial heads, rods, locking caps, connectors, hooks and associated general instruments. The implant components are available in a variety of sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The purpose of this submission is to add components like additional polyaxial heads, cannulated screws, fenestrated screws, screws with larger diameters and lengths and hooks and connectors to the MOSS VRS Spinal System (see K181821).

The safety and effectiveness of the fenestrated screws 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.

All implants of the MOSS VRS System are single-use only and the system is provided non sterile.

Material

The implants are manufactured from ASTM F 136 implant grade titanium alloy Ti-6Al-4V ELI and cobalt chromium alloy according to ASTM F1537.

Indication for Use

The MOSS VRS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.
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Technological Characteristics and Substantial Equivalence

As was established in this submission, the subject MOSS VRS Spinal System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States.

The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, labeling, intended use, material composition and function.

Performance Data

The new additional components of the MOSS VRS Spinal System were evaluated per the FDA Guidance Document for Industry and FDA Staff; Spinal System 510(k)s.

The following mechanical testing was carried out to show safety and effectiveness of our system:

Bench testing – mechanical

Mechanical testing according to ASTM F1717 (Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model) standard and to ASTM F1798 (Standard Test Method 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 were performed to support system related performance under consideration of well-established acceptance criteria. Performance testing included:

- ASTM F1717:
  - Static Compression
  - Dynamic Compression
  - Static Torsion
- ASTM F1798:
  - Static Flexion Extension
  - Dynamic Flexion Extension
  - Static Axial Grip
  - Static Axial Pull-Off

Result: The results demonstrate that the MOSS VRS Spinal System is substantially equivalent to the identified predicate devices.

Substantial Equivalence Summary and Conclusion

The subject MOSS VRS Spinal System can be considered substantially equivalent to legally marketed predicate devices.