



October 22, 2019

MiRus, LLC
Jordan Bauman
Vice President, Regulatory Affairs
1755 West Oak Parkway, Suite 100
Marietta, Georgia 30062

Re: K192268

Trade/Device Name: Europa Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 3, 2019
Received: September 4, 2019

Dear Jordan Bauman:

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,

for

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192268

Device Name

EUROPA™ Pedicle Screw System

Indications for Use (Describe)

The EUROPA™ Pedicle Screw 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 EUROPA™ Pedicle Screw System is intended for posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (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; and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

I. SUBMITTER

MiRus™, LLC
 1755 West Oak Parkway
 Suite 100
 Marietta, Georgia 30062
 Tel: (678)-324-6272
 Fax: (678) 401-5607

II. OFFICIAL CORRESPONDENT

Jordan Bauman
 Vice President, Regulatory Affairs
 MiRus™, LLC
 1755 West Oak Parkway
 Suite 100
 Marietta, Georgia 30062
 Tel: (678)-324-6272
 Fax: (678) 401-5607

III. DATE PREPARED

October 21, 2019

IV. DEVICE

Name of Device	EUROPA™ Pedicle Screw System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	21 CFR §888.3070
Regulatory Class	Class II
Product Codes	NKB
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

EUROPA™ Pedicle Screw System (K180337, K182970, K191757) [Primary Predicate]

VI. DEVICE DESCRIPTION

The EUROPA™ Pedicle Screw System is comprised of both Open and Minimally Invasive Surgery (MIS) polyaxial pedicle screw and rod components that are available in different sizes to accommodate various patient anatomical and physiological requirements.

The pedicle screws are manufactured from Ti-6Al-4V ELI alloy (ASTM F136). The rods are manufactured from Molybdenum-47.5Rhenium alloy (ASTM F3273) or cobalt chromium alloy (ASTM F1537).

The system also includes adjustable-length transverse rod cross connectors manufactured from Ti-6Al-4V ELI alloy (ASTM F136-13) that may be used in EUROPA™ systems with cobalt chromium rods where increased structural rigidity of the construct is needed.

The purpose of this 510(k) submission is to obtain market clearance for additional EUROPA™ Pedicle Screw System rod to rod connectors manufactured from Ti-6Al-4V ELI alloy (ASTM F136-13) which may be used to connect or extend constructs in an in-line or parallel fashion.

VII. INDICATIONS FOR USE

The EUROPA™ Pedicle Screw 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 EUROPA™ Pedicle Screw System is intended for posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (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; and failed previous fusion.

VIII. PREDICATE DEVICE COMPARISON

The purpose of this 510(k) submission is to obtain market clearance for additional EUROPA™ Pedicle Screw System rod to rod connectors. All other aspects of the subject device are identical to the predicate device.

IX. PERFORMANCE DATA

The following performance testing was completed in accordance with ASTM F1798:

- Axial (z) Gripping Capacity (Axial Grip)
- Axial Torque (Mz) Gripping Capacity (Torsional Grip)
- Flexion-Extension Moment (My)

The results demonstrate the performance of the EUROPA™ Pedicle Screw System with rod connectors are substantially equivalent to legally marketed devices.

X. CONCLUSION

The EUROPA™ Pedicle Screw System with rod to rod connectors is substantially equivalent to the predicate devices in intended use, indications for use, technological characteristics and labeling.