January 22, 2019

MiRus, LLC
Mr. Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway SE, Suite 108
Marietta, Georgia 30067

Re: K182970
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: October 25, 2018
Received: October 26, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182970

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.

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510(k) Summary

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

I. SUBMITTER

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II. OFFICIAL CORRESPONDENT

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Fax: (678) 401-5607

III. DATE PREPARED

October 25, 2018

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

Primary Predicate
EXPEDIUM® Spine System - K082942
Additional Predicates
EXPEDIUM® Spine System - K041801
EXPEDIUM® Spine System - K071495
EXPEDIUM® Spine System - K041119

VI. DEVICE DESCRIPTION

The EUROPA™ Pedicle Screw System is a rigid thoracolumbosacral pedicle screw system as defined in 21 CFR 888.3070. The 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.

VII. MATERIALS

The device is manufactured from ASTM F136 implant grade titanium alloy and ASTM F1537 cobalt chrome alloy.

VIII. 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.

IX. PREDICATE DEVICE COMPARISON

The intended use and technological characteristics (e.g., design, materials, principles of operations) of the EUROPA™ Pedicle Screw System are the same as the predicate device.

X. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- static and dynamic compression bending - ASTM F1717
- static torsion - ASTM F1717

XI. CONCLUSONS

The performance data demonstrate that the EUROPA™ Pedicle Screw System is substantially equivalent to the predicate device.