November 19, 2024

MiRus, LLC
Anuradha Nagulapati
Senior Regulatory Affairs Engineer
1755 W. Oak Parkway
Suite 100
Marietta, Georgia 30062

Re: K242516
Trade/Device Name: EUROPA™ Posterior Cervical Fusion System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: August 23, 2024
Received: August 23, 2024

Dear Anuradha Nagulapati:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

RYAN TROMBETTA -S

Digitally signed by RYAN TROMBETTA -S
Date: 2024.11.19 16:46:24 -05'00'

For: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242516

Device Name

EUROPA™ Posterior Cervical Fusion System

Indications for Use *(Describe)*

The EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Failed previous fusions (e.g. pseudarthrosis)
- Tumors involving the cervical/thoracic spine
- Degenerative disease, including intractable radiculopathy and/or myelopathy
- Neck and/or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability

The EUROPA™ Posterior Cervical Fusion System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod to rod connectors.

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

Prepared on: 2024-11-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MiRus, LLC
Applicant Address	1755 W. Oak Parkway Suite 100 Marietta GA 30062 United States
Applicant Contact Telephone	470-428-8684
Applicant Contact	Ms. Anuradha Nagulapati
Applicant Contact Email	anagulapati@mirusmed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EUROPA™ Posterior Cervical Fusion System
Common Name	Posterior cervical screw system
Classification Name	Posterior Cervical Screw System
Regulation Number	888.3075
Product Code(s)	NKG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182508	Saxxony™ Posterior Cervical Thoracic System	NKG
K180337	EUROPA™ Pedicle Screw System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The EUROPA™ Posterior Cervical Fusion System is a posterior cervical screw system intended to provide structural stability and mechanical support to the cervical spine following posterior cervical fusion.

The EUROPA™ Posterior Cervical Fusion System consists of rods manufactured from Molybdenum-47.5 Rhenium Alloy (MoRe) per ASTM F3273, pedicle screws and connectors manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136, and instrumentation manufactured from Stainless Steel per ASTM F899. The EUROPA™ Posterior Cervical Fusion System implants are offered in multiple configurations and different sizes to accommodate various patient anatomical requirements.

The rods are provided sterile packed and are intended for single use only. The pedicle screws and connectors must be steam sterilized prior to use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Failed previous fusions (e.g. pseudarthrosis)

- Tumors involving the cervical/thoracic spine
- Degenerative disease, including intractable radiculopathy and/or myelopathy
- Neck and/or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability

The EUROPA™ Posterior Cervical Fusion System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod to rod connectors.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for the use are identical for the subject device and predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The EUROPA™ Posterior Cervical Fusion System has the same intended use, indications for use, labeling, and technological characteristics as the predicate system, including the same design features, geometries, sizes, and materials. The predicate device components are manufactured from titanium alloy (ASTM F136) and cobalt chromium alloy (ASTM F1537). The EUROPA™ Posterior Cervical Fusion System components are manufactured from titanium alloy (ASTM F136) and molybdenum-rhenium alloy (ASTM F3273), which are the same materials as the reference device. Performance data demonstrate that the EUROPA™ Posterior Cervical Fusion System is substantially equivalent to other legally marketed predicate systems.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The mechanical performance profile of the EUROPA™ Posterior Cervical Fusion System was assessed through static and dynamic testing in accordance with the following test methods:

- Static and dynamic compression bending testing (ASTM F1717-21)
- Static torsion testing (ASTM F1717-21)
- Axial gripping strength testing (ASTM F1798-21)
- Axial torque gripping strength testing (ASTM F1798-21)

The EUROPA™ Posterior Cervical Fusion System has the same intended use, indications for use, labeling, and technological characteristics as the predicate system, including the same design features, geometries, sizes, and materials. The predicate device components are manufactured from titanium alloy (ASTM F136) and cobalt chromium alloy (ASTM F1537). The EUROPA™ Posterior Cervical Fusion System components are manufactured from titanium alloy (ASTM F136) and molybdenum-rhenium alloy (ASTM F3273), which are the same materials as the reference device. Performance data demonstrate that the EUROPA™ Posterior Cervical Fusion System is substantially equivalent to other legally marketed predicate systems.