



March 18, 2026

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

Re: K253444

Trade/Device Name: EUROPA™ Posterior Cervical Fusion Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 16, 2026
Received: February 17, 2026

Dear Ms. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,



Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K253444

Device Name

EUROPA™ Posterior Cervical Fusion Navigated Instruments

Indications for Use (Describe)

The EUROPA™ Posterior Cervical Fusion Navigated Instruments are intended to be used in the preparation and placement of the EUROPA™ Posterior Cervical Fusion screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the stereotactic navigation system Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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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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 Navigated Instruments
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	OLO

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140454	Navigated CD HORIZON SOLERA Screwdrivers and Taps	OLO
K143628	Navigated VERTEX SELECT Instruments	OLO

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The EUROPA™ Posterior Cervical Fusion Navigated Instruments are intended to be used with the EUROPA™ Posterior Cervical Fusion System screws. The EUROPA™ Posterior Cervical Fusion Navigated Instruments consist of non-sterile, re-usable instruments including probes, drivers, awls, drills, and taps that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System and are manufactured from Stainless Steel per ASTM F899.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The EUROPA™ Posterior Cervical Fusion Navigated Instruments are intended to be used in the preparation and placement of the EUROPA™ Posterior Cervical Fusion screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the stereotactic navigation system Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Indications for Use of the subject device are substantially equivalent to those of the predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The EUROPA™ Posterior Cervical Fusion Navigated Instruments have the same intended use, indications for use, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials. Performance data demonstrate that the EUROPA™ Posterior Cervical Fusion Navigated Instruments are substantially equivalent to the predicate systems.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The EUROPA™ Posterior Cervical Fusion Navigated Instruments have been evaluated through comparative dimensional analyses showing equivalent critical geometry of the instruments and their array connection interfaces to the corresponding Medtronic StealthStation instrument counterparts.

The results of the engineering analyses show that the subject devices are substantially equivalent to the cleared predicates.

The EUROPA™ Posterior Cervical Fusion Navigated Instruments have the same intended use, indications for use, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials. Performance data demonstrate that the EUROPA™ Posterior Cervical Fusion Navigated Instruments are substantially equivalent to the predicate systems.