June 23, 2023

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

Re: K230369
Trade/Device Name: EUROPA™ Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 10, 2023
Received: February 10, 2023

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,

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

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)*

K230369

Device Name

EUROPA™ Navigated Instruments

Indications for Use *(Describe)*

The EUROPA™ Navigated Instruments are intended to be used in the preparation and placement of the EUROPA™ pedicle 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.

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

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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

Jordan Bauman

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Fax: (678) 401-5607

III. DATE PREPARED

May 22, 2023

IV. DEVICE

Name of Device	EUROPA™ Navigated Instruments
Common Name	Orthopedic Stereotaxic Instrument
Classification Name	21 CFR 882.4560
Regulatory Class	Class II
Product Codes	OLO
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Primary Predicate
Medtronic Navigated Instruments – Medtronic Inc. (K140454)
Additional Predicates
Medtronic Navigated Instruments – Medtronic Inc. (K143628, K143375)
Reference Device
EUROPA™ Pedicle Screw System - MiRus, LLC (K182970, K180337)

VI. DEVICE DESCRIPTION

The EUROPA™ Navigated Instruments is intended to be used with the EUROPA™ Pedicle Screw System. The EUROPA™ Navigated Instruments are non-sterile, re-usable instruments including probes, taps, and drivers 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.

VII. INDICATIONS FOR USE

The EUROPA™ Navigated Instruments are intended to be used in the preparation and placement of the EUROPA™ pedicle 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.

VIII. PREDICATE DEVICE COMPARISON

The EUROPA™ Navigated Instruments have similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

IX. PERFORMANCE DATA

The mechanical performance profile of the EUROPA™ Navigated Instruments was assessed through design validation testing. Design validation testing included testing per ASTM F2554-18, and a one-to-one dimensional comparison to demonstrate substantially equivalent geometry that is critical to navigation accuracy. Testing, including anatomical and navigated simulated use and accuracy and reliability testing, has been conducted to verify that the EUROPA™ Navigated Instruments are appropriate for their intended use, to ensure functionality, accuracy, and compatibility with the Medtronic StealthStation® System using the NavLock Tracker, and to demonstrate substantial equivalence to the predicate instruments.

X. CONCLUSIONS

The EUROPA™ Navigated Instruments have similar intended use, indications for use, labeling, and technological characteristics as the predicate system, including design features, geometries, sizes, and materials. Performance data demonstrate that the EUROPA™ Navigated Instruments is substantially equivalent to legally marketed predicate systems.