August 7, 2024

Spineart SA
Estelle Lefeuvre
Regulatory & Market Access Manager
Chemin du Pré-Fleuri 3
Plan-les-Ouates, 1228
Switzerland

Re: K241644
Trade/Device Name: SPINEART Navigation Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 5, 2024
Received: June 7, 2024

Dear Estelle Lefeuvre:

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.

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

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)*

K241644

Device Name

SPINEART Navigation Instrument System

Indications for Use *(Describe)*

The Spineart Navigation Instrument System reusable instruments are intended to be used during the preparation and placement of Spineart screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Spineart Navigation Instrument System reusable instruments are specifically designed for use with the 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 a long bone or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for 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.

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Special 510k
SPINEART Navigation Instrument System

510(k) SUMMARY

510k	Special
Basis for submission	New devices
Submitted by	SPINEART SA 3 Chemin du Pré Fleuri 1228 Plan-les-Ouates SWITZERLAND
Contacts	Estelle LEFEUVRE, Regulatory & Market Access Manager Phone : +41 22 570 1200 Fax : +41 22 594 8306 Mail : elefeuvre@spineart.com Regulatory contact : Estelle LEFEUVRE (elefeuvre@spineart.com)
Date Prepared	June 5th, 2024
Common Name	Orthopedic Stereotaxic Instrument
Trade Name	SPINEART Navigation Instrument System
Classification Name	Orthopedic Stereotaxic Instrument
Class	II
Product Code	OLO
CFR section	882.4560
Device panel	Orthopedic
Legally marketed predicate devices	Primary predicate: SPINEART Navigation Instrument System manufactured by SPINEART (K183630, K210472)
Indications for use	The SPINEART® Navigation Instrument System reusable instruments are indicated to be used during the preparation and placement of Spineart screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SPINEART® Navigation Instrument System reusable instruments are specifically designed for use with the 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 a long bone or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Description of the device	The SPINEART® Navigation Instrument System reusable instruments are surgical instruments for use with the Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. The SPINEART® Navigation system includes the following instruments dedicated to screw placement: Screwdrivers, Taps, Drills. The SPINEART® Navigation Instrument System is to be used with the following Spineart Systems: ▪ Romeo®2 ▪ Romeo®2 MIS ▪ Perla® ▪ Perla® TL ▪ Perla® TL MIS All instruments are made of stainless steel per ASTM F899. All instruments are reusable instruments provided non sterile. The SPINEART® Navigation Instrument System instruments are not compatible with implants from other manufacturers. The SPINEART® Navigation Instrument System are designed for use only with Medtronic StealthStation® System (V2.1.0) and the Medtronic NavLock® Tracker System.
Technological characteristics compared to the predicate devices	The subject product line extension of the SPINEART® Navigation Instrument System (K183630, K210472) consists of addition of drills and screwdrivers for the Perla TL Posterior Osteosynthesis System and Perla Posterior Occipito-cervico-thoracic Fixation System. As was established in this submission, the SPINEART® Navigation added instruments are substantially equivalent and have the same technological characteristics to predicate devices in areas including indications for use, function, material composition, design, range of sizes and accuracy performance. Verification and validation activities conducted on the added navigated instruments demonstrate that these navigated instruments are suitable to be used with the Medtronic StealthStation® System (V2.1.0) and the Medtronic NavLock® Tracker System when implanting screws part of the Perla TL Posterior Osteosynthesis System and Perla Posterior Occipito-cervico-thoracic Fixation System.
Discussion of Testing	Addition of navigated instruments to SPINEART® Navigation Instrument System (K183630, K210472) does not require testing. An Engineering Analysis has been submitted to support substantial equivalence.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and dimensional and tolerance stack-up analysis, the added SPINEART® Navigation Instruments have demonstrated substantial equivalence to the identified predicate devices.