April 9, 2026

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

Re: K254158
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: December 22, 2025
Received: December 22, 2025

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 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254158

Please provide the device trade name(s).

SPINEART Navigation Instrument System

Please provide your Indications for Use below.

The SPINEART Navigation 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 reusable instruments are specifically designed for use with the Medtronic® StealthStation® System and the Brainlab® Spine & Trauma Navigation System, which are 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K254158

510(k) Summary

Prepared on: 2026-04-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Spineart SA
Applicant Address	Chemin du Pré-Fleuri 3 Plan-les-Ouates 1228 Switzerland
Applicant Contact Telephone	0041225701203
Applicant Contact	Ms. Estelle Lefeuvre
Applicant Contact Email	elefeuvre@spineart.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SPINEART Navigation Instrument System
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
K212245	Spine and Trauma Navigation System	OLO
K201189	Stealthstation S8 Spine Software v1.3.0	OLO
K183630	SPINEART Navigation Instrument System	OLO
K210472	SPINEART Navigation Instrument System	OLO
K241644	SPINEART Navigation Instrument System	OLO
K242933	SPINEART Navigation Instrument System	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The SPINEART® Navigation Instrument System reusable instruments are surgical instruments for use with the Medtronic® StealthStation® Navigation System and Brainlab® Spine and Trauma 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, Probes and Drills.
The SPINEART® Navigation Instrument System is to be used with the following Spineart Systems:
- Romeo®2
- Romeo®2 MIS
- Perla®
- Perla® TL, including pelvic fixation add-on system
- 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SPINEART Navigation 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 reusable instruments are specifically designed for use with the Medtronic® StealthStation® System and the Brainlab® Spine & Trauma Navigation System, which are 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The subject product line extension of the SPINEART® Navigation Instrument System (K183630, K210472, K241644, K242933) consists of addition of taps, screwdrivers and probes for the PERLA® TL Posterior Thoraco-lumbar Fixation System.
The material, design features and sizing of the line extension of Navigated Instruments were developed with the same specifications as the predicate devices, therefore there are no significant differences between this line extension and these 510(k) approved predicate devices.
For these reasons, we can conclude that there is no significant change on the product range which would adversely affect the use and performances of the product.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

No non-clinical and/or clinical testing was required for the subject device. A geometric comparison to predicate devices established the safety and efficacy for accuracy performance.