March 7, 2025

Spineart Sa
Estelle Lefeuvre
Regulatory & Market Access Manager
3 chemin du Pré-Fleuri
Plan Les Ouates, 1228
Switzerland

Re: K242890
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: September 23, 2024
Received: February 6, 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 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,

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)*

K242890

Device Name

SPINEART Navigation Instrument System

Indications for Use *(Describe)*

The SPINEART Navigation reusable instruments are intended to be used during the preparation and placement of SPINEART PERLA TL screws during thoracolumbar 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 eCential Op.n PERLA® TL Nav System. It is indicated for population with medical conditions requiring the placement of spinal screws and for which the use of stereotactic surgery may be considered to be appropriate and where reference to a rigid anatomical structure, such as a vertebra, can be identified. The guidance is based on an intra-operative surgical plan developed with Op.n PERLA® TL Nav Software and based on intraoperative 3D images provided by a compatible imaging system.

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.

510(k) #: K242890

510(k) Summary

Prepared on: 2025-02-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SPINEART SA
Applicant Address	3 chemin du Pré-Fleuri PLAN LES OUATES 1228 Switzerland
Applicant Contact Telephone	+41 22 570 1203
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	Orthopedic Naviagated instruments
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
K210472	SPINEART Navigation Instrument System	OLO
K231886	SURGIVISIO Device	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The Spineart® Navigation reusable instruments are surgical instruments to be used with a 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. Currently cleared Spineart® Navigation reusable instruments (K210472) feature a connecting area for the tracker compatible with the Navlock Tracker to be navigated with the Medtronic® StealthStation® Navigation System. The purpose of this submission is to get clearance to include Spineart's eCential® Navigation Adapter (subject device) designed to enable navigation of Spineart Navigation Instruments with the eCential® Op.n® Navigation System to the cleared range of SPINEART® Navigation Instrument System.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SPINEART Navigation reusable instruments are intended to be used during the preparation and placement of SPINEART PERLA TL screws during thoracolumbar 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 eCential Op.n PERLA® TL Nav System. It is indicated for population with medical conditions requiring the placement of spinal screws and for which the use of stereotactic surgery may be considered to be appropriate and where reference to a rigid anatomical structure, such as a vertebra, can be identified. The guidance is based on an intra-operative surgical plan developed with Op.n PERLA® TL Nav Software and based on intraoperative 3D images provided by a compatible imaging system.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Compared to predicate devices (K210472) the only modification to the indications for use is to add the option of using the SPINEART Navigation Reusable Instrument system with the eCential® Op.n® Navigation System through the introduction of a SPINEART eCential® Navigation Adaptor and the Nav. Bs Checking Tip. The added SPINEART eCential® Navigation Adaptor and Nav. Bs Checking Tip do not alter the intended use of the SPINEART Navigation Reusable Instrument system.

Technological Comparison

21 CFR 807.92(a)(6)

The intended use, design features, technological characteristics, feature comparisons and performance assessment of the subject SPINEART Navigation Reusable Instrument system remain the same as predicate devices (SPINEART Navigation Reusable Instrument system K210472). It has been established that the addition of the SPINEART eCential® Navigation Adaptor on the SPINEART Navigation reusable instruments for a use with the eCential® Op.n® Navigation System does not raise accuracy issues. The Nav. Bs Checking Tip is not involved in the accuracy. The added SPINEART eCential® Navigation Adaptor does not affect the safety and effectiveness of the device relative to the predicate (SPINEART Navigation Reusable Instrument system K210472). Based on the comparison to the predicates and the performance testing conducted, the subject devices are considered substantially equivalent to the predicate devices (K210472).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following testing were conducted on the SPINEART instruments to establish substantial equivalence with the predicate devices:
-ASTM F2554 Verification: Verification of the eCential® Navigation Adaptor designed by Spineart used in a worst case scenario, with the eCential® Op.n® Perla TL Nav system, according to the ASTM F2554 protocole
- Accuracy Verification: Verification of the accuracy of the SPINEART Navigation reusable instruments with the eCential® Op.n® Perla TL Nav system, according a Protocole defined by eCential®. Performance data showed that the Navigation of the SPINEART Navigation reusable instruments with the eCential® Op.n® Perla TL Nav system using the eCential® Navigation adaptor provides an accuracy equivalent to the acceptance criteria initially defined for the compatbility of the SPINEART Navigation reusable instruments when used with the Medtronic® Stealthstation® System.
No clinical testing was required for the subject device.

"Not Applicable."

It has been demonstrated that the addition of the SPINEART eCential® Navigation Adaptor (subject device) on the SPINEART Navigation reusable instruments (predicate device) for a use with the eCential® Op.n® Perla TL Nav system does not raise accuracy issues.