



July 29, 2026

Spineart SA
Estelle Godeau
Regulatory Affairs & Market Access Director
Chemin Du Pré-Fleuri 3
Plan-Les-Ouates, 1228
Switzerland

Re: K261205

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 29, 2026
Received: June 29, 2026

Dear Estelle Godeau:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

K261205

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Please provide the device trade name(s).

?

SPINEART Navigation Instrument System

Please provide your Indications for Use below.

?

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 eCential Op.n PERLA® TL Nav or with Perla by Spineart device. It is indicated for population with medical conditions requiring the placement of thoracolumbar 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 or with Perla by Spineart software and based on intra-operative 3D images provided by a compatible imaging system. eCential Op.n PERLA® TL Nav device is intended to be used for thoracolumbar vertebrae surgery. eCential Perla by Spineart device is intended to be used for thoracolumbar + S1 vertebrae surgery.

The SPINEART Robotic 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 Robotic reusable instruments are specifically designed for use with eCential Perla by Spineart device. It is indicated for population with medical conditions requiring the placement of thoracolumbar spinal screws and for which the use of stereotactic surgery with robotic arm guidance, 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 Perla by Spineart software, followed by related robotic arm positioning and instrument guiding, and checked on intra-operative 3D images provided by a compatible imaging system.

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](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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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 Godeau
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
K210472, K241644	SPINEART Navigation Instrument System	OLO
K261113	Op.n™ Spine Navigation and Robotic Guidance	OLO

Device Description Summary

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

The SPINEART Navigation reusable instruments are surgical instruments for use with the eCential Op.n PERLA® TL Nav or with Perla by Spineart software in Navigation mode, 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. All instruments are made of stainless steel per ASTM F899.

The SPINEART Navigation Instruments include the following: Screwdrivers, Taps, Drills, Probes of the Perla® TL Posterior Thoraco-Lumbar Fixation System (MIS and Open).

The SPINEART Navigation Instruments are designed for use with eCential Op.n PERLA® TL Nav or Perla by Spineart device.

The SPINEART Navigation instruments are NOT compatible with implants from other manufacturers.

Only SPINEART implants included in the Op.n Perla® TL Nav software or Perla by Spineart software are to be used with the eCential Op.n PERLA® TL Nav or Perla by Spineart device.

The SPINEART Robotic Reusable instruments are surgical instruments for use with eCential Perla by Spineart in Navigation mode and/or robotic guidance mode, 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. All instruments are made of stainless steel per ASTM F899.

The SPINEART Robotic Reusable instruments include the following: Screwdrivers and Taps for Perla® TL Posterior Thoraco-Lumbar Fixation System (MIS and Open), coupled with a Robotic Adaptor.

The SPINEART Robotic Reusable Instruments are designed for use with eCential Perla by Spineart device.

The SPINEART Robotic Reusable instruments are NOT compatible with implants from other manufacturers.

Only SPINEART implants included in the Perla by Spineart software are to be used with the eCential Perla by Spineart device.

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 eCential Op.n PERLA® TL Nav or with Perla by Spineart device. It is indicated for population with medical conditions requiring the placement of thoracolumbar 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 or with Perla by Spineart software and based on intra-operative 3D images provided by a compatible imaging system. eCential Op.n PERLA® TL Nav device is intended to be used for thoracolumbar vertebrae surgery. eCential Perla by Spineart device is intended to be used for thoracolumbar + S1 vertebrae surgery.

The SPINEART Robotic 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 Robotic reusable instruments are specifically designed for use with eCential Perla by Spineart device. It is indicated for population with medical conditions requiring the placement of thoracolumbar spinal screws and for which the use of stereotactic surgery with robotic arm guidance, 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 Perla by Spineart software, followed by related robotic arm positioning and instrument guiding, and checked on intra-operative 3D images provided by a compatible imaging system.

Indications for Use Comparison

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

Compared to the predicate devices K210472, K241644, K242890 and K254158, the modification to the indications for use is to add the option of using the already cleared SPINEART Navigation Reusable Instrument System with the Op.n™ Spine Navigation and Robotic Guidance for Free hand Navigation flow and the subject devices with the Op.n™ Spine Navigation and Robotic Guidance through robotic arm guidance.

Technological Comparison

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

The design features, material, technological characteristics and feature comparisons of the subject SPINEART Navigation Reusable Instrument system are similar as predicate devices (SPINEART Navigation Reusable Instrument system K210472, K241644, K242890 and K254158).

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

Lifetime and mechanical verification tests as well as an accuracy budget evaluation were performed on the subject devices. This included dimensional comparison analysis to directly compare the key physical and geometric specifications of the subject device to those of the predicate device.

Design verification testing was conducted to evaluate component assembly, tolerance stacking, and instrument registration with the navigation system.

Summative usability validation testing was conducted using cadaver specimens.

No clinical testing was required for the subject device.

The SPINEART Navigation reusable instruments (subject devices) are verified for use with Op.n Spine Navigation and Robotic Guidance. The new features with respect to predicate devices have been identified and successfully tested. The accuracy budget meets all the acceptance criteria. There are no significant differences between this new range of instruments and the predicate devices that would adversely affect the use and performance of the product.