July 22, 2026

Ecential Robotics
Elodie Bouillet
Quality and Regulatory Affairs Manager
2 Ave. De Vignate
Zone Mayencin Ii, Parc Equation - Bâtiment 1
Gieres, 38610
France

Re: K261113
Trade/Device Name: Op.n™ Spine Navigation and Robotic Guidance
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 2, 2026
Received: July 2, 2026

Dear Elodie Bouillet:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), titled “Op.n™ Spine Navigation and Robotic Guidance – Predetermined Change Control Plan”, version C. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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

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.

510(k) Number *(if known)*
K261113

Device Name
Op.n™ Spine Navigation and Robotic Guidance

Indications for Use *(Describe)*
Op.n™ Spine Navigation and Robotic Guidance, when used with an Op.n™ Spine Navigation and Robotic Guidance Software, is intended for the spatial positioning and orientation of compatible surgical instruments to be used by surgeons during general spinal surgery, in Instruments navigation mode and/ or robotic guidance mode.
The instrument navigation mode and the robotic guidance mode are based on patient 3D image data, on which the surgeon may perform an intraoperative surgical planning.

Op.n™ Spine Navigation and Robotic Guidance Software is a surgical navigation software. It is intended to provide guidance for the positioning of compatible surgical instruments to be used by surgeons. The software is indicated for the placement of spinal bone screws, in instrument navigation mode and/or robotic guidance mode, in vertebrae with a posterior approach in the thoracolumbar and sacral regions.

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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510(k) Summary

Administrative Information

510(k) Applicant:	eCential Robotics
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Company Contact Person:	Elodie BOUILLET
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Email:	fda@ecential-robotics.com

Date Summary Prepared:	March 27th 2026

Device Information

Device trade or proprietary name:	**Op.n™ Spine Navigation and Robotic Guidance**
Device Common name:	Orthopedic Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument
Classification Regulation:	21 CFR 882.4560
Regulatory class:	Class II
Device Panel	Orthopedic
Device product code:	OLO

Predicate 510(k):

- K242914 Op.n™ Navigation
- K233228 Spine Navigation and Robotic-Assistance Device

Device Description:

The **Op.n™ Spine Navigation and Robotic Guidance** is a medical device that consists of a software, called **Op.n™ Spine Navigation and Robotic Guidance Software**, and a set of associated devices composed of surgical instruments and electromedical equipment.

The **Op.n™ Spine Navigation and Robotic Guidance Software** is installed on the **Op.n™ Core Station** and interfaces with navigated instruments, accessories and third-party surgical instruments. The software displays the intraoperative location of navigated surgical instruments relative to imported 3D volumes via wireless optical tracking technology. The **Op.n™ Spine Navigation and Robotic Guidance Software** is an interactive software application, which provides the functions needed to conduct the indicated spine procedures. The software application implements the methods for patient registration, planning screws' positions and then instrument guidance for preparation of pilot holes.

The **Op.n™ Spine Navigation and Robotic Guidance** interfaces with Third-Party surgical instruments to navigate them for placement of the spinal bone screws. Pilot hole preparation as well as navigation and placement of spinal

bone screws can be done in instrument navigation mode or robotic guidance mode.

Indication for use:

Op.n™ Spine Navigation and Robotic Guidance, when used with an Op.n™ Spine Navigation and Robotic Guidance Software, is intended for the spatial positioning and orientation of compatible surgical instruments to be used by surgeons during general spinal surgery, in Instrument Navigation Mode and/ or Robotic Guidance Mode.
The Instrument Navigation Mode and the Robotic Guidance Mode are based on patient 3D image data, on which the surgeon may perform an intraoperative surgical planning.
Op.n™ Spine Navigation and Robotic Guidance Software is a surgical navigation software. It is intended to provide guidance for the positioning of compatible surgical instruments to be used by surgeons. The software is indicated for the placement of spinal bone screws, in Instrument Navigation Mode and\or Robotic Guidance Mode, in vertebrae with a posterior approach in the thoracolumbar and sacral regions.

Summary of the technological characteristics of the device compared to the predicate device

The **Op.n™ Spine Navigation and Robotic Guidance** is substantially equivalent to the Op.n™ Navigation, as a primary predicate and Spine Navigation and Robotic-Assistance Device, as a secondary predicate.

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
INDICATIONS FOR USE				
Intended Use	- Spatial positioning and orientation of compatible surgical instruments - used in Instrument Navigation Mode and/or in Robotic-Assisted Guidance Mode	- Spatial positioning and orientation of compatible surgical instruments - used in Instrument Navigation Mode and/or in Robotic-Assisted Guidance Mode	- Spatial positioning and orientation of compatible surgical instruments - used in Freehand Navigation Guidance Mode and/or in Robotic-Assisted Guidance Mode	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Indications for use	**Op.n™ Spine Navigation and Robotic Guidance**, when used with an **Op.n™ Spine Navigation and Robotic Guidance Software**, is intended for the spatial positioning and orientation of compatible surgical instruments to be used by surgeons during general spinal surgery, in Instruments navigation mode and/ or robotic-assisted guidance mode. The instrument navigation mode and the robotic-assisted guidance mode are based on patient 3D image data, on which the surgeon may perform an intraoperative surgical planning. **Op.n™ Spine Navigation and Robotic Guidance Software** is a surgical navigation software. It is intended to provide guidance for the positioning of compatible surgical instruments to be used by surgeons. The software is indicated for the placement of spinal bone screws, in instrument navigation mode and\or robotic-assisted guidance mode, in vertebrae with a posterior approach in the thoracolumbar and sacral regions.	Op.n™ Navigation is indicated for the positioning of compatible surgical instruments to be used by surgeons during general spinal surgery. The guidance is based on an intra-operative surgical plan developed with Op.n™ Navigation Software and based on intra-operative 3D images provided by a compatible imaging system. The device is indicated for the placement of pedicle screws, instrument navigation mode, in vertebrae with a posterior approach in the thoracolumbar region. Op.n™ Navigation Software is indicated for the navigation of compatible surgical instruments to be used by surgeons.	Spine Navigation and Robotic-Assistance Device is indicated for the spatial positioning and orientation of compatible surgical instruments, used by surgeons in Freehand Navigation Mode and/or in Robotic-Assisted Guidance Mode. Spine Navigation and Robotic-Assistance Device is used for spine surgeries, in open or percutaneous procedures, with patient in prone or in lateral position. Freehand Navigation Mode and Robotic-Assisted Guidance Mode are based on a three-dimensional image volume (3D CT or CBCT image), on which the surgeon may perform the Intraoperative Surgical Planning. Spine Navigation and Robotic-Assistance Device is indicated to provide guidance for the placement of spinal bone screws relative to bony structures of the spine, in Freehand Navigation Mode and/or in Robotic-Assisted Guidance Mode, and for intervertebral disc access and preparation, including discectomy and bony resection, in Freehand Navigation Mode.	SUBSTANTIALLY EQUIVALENT to both predicates
Anatomical site	Thoracolumbar and sacral region	Thoracolumbar region	Spine	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Patient Population	A population with medical conditions requiring the placement of spinal bone screws and for which the use of stereotactic surgery may be considered to be appropriate. Careful considerations shall be given to the compatibility of patient spinal anatomy with patient fixation, the possibility of using surgical instruments in instrument navigation mode or robotic-assisted guidance mode, and also the dimensions of spinal bone screw proposed by the **Op.n™ Spine Navigation and Robotic Guidance**'s surgical plan.	A population with medical conditions requiring the treatment of diseases with the placement of spinal instruments and for which the use of stereotactic surgery may be considered to be appropriate and after consideration of the compatibility of patient spinal anatomy with dimensions of the Spine CoBot Instruments and dimensions of virtual implants proposed by the 3D Spine Robotics workflow surgical plan.	A patient for which the use of stereotactic surgery may be appropriate.	SUBSTANTIALLY EQUIVALENT to both predicates
Contra indications	Medical conditions which contraindicate the use of the subject device and its associated applications include any medical conditions which may contraindicate the medical procedure itself. No other contraindications related to the use of robotic assistance in spine surgery have been identified in the literature.	Medical conditions which contraindicate the use of the assessed device and its associated applications include any medical conditions which may contraindicate the medical procedure itself. No other contraindications related to the use of robotic assistance in spine surgery have been identified in the literature.	Medical conditions which contraindicate the use of the device, and its associated applications include any medical conditions which may contraindicate the medical procedure itself.	SUBSTANTIALLY EQUIVALENT to both predicates
Environment of use	Operating Room	Operating Room	Operating room	IDENTICAL to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
User	Intended to be used primarily by trained neurosurgeons and orthopedic spine surgeons.	Intended to be used primarily by trained neurosurgeons and orthopedic surgeons.	Qualified medical professionals trained on the proper use of the system.	SUBSTANTIALLY EQUIVALENT to both predicates
TECHNOLOGICAL CHARACTERISTICS				
General technology description	Computer-controlled electromechanical arm guiding spinal surgical instruments.	Computer-controlled electromechanical arm guiding spinal surgical instruments.	Computer-controlled electromechanical arm guiding neurosurgical instruments	SUBSTANTIALLY EQUIVALENT to both predicates
Principles of operation of the Robotic-Assisted Guidance mode	Stereotactic Robotic-Assisted Guidance of spinal surgical instruments relying on an intraoperative plan based on intraoperative 3D image using an optical system (infrared camera).	Stereotactic robotic navigation guidance of spine surgical instruments based on an intra-operative plan developed with three-dimensional imaging software which is based on intraoperative 3D images using an optical system (infrared camera).	Stereotactic Robotic-Assisted Guidance of spinal surgical instruments relying on an intraoperative plan based on intraoperative 3D image using an optical system (infrared camera).	SUBSTANTIALLY EQUIVALENT to both predicates
Principles of operation of the Instrument Navigation Mode	Stereotactic Instrument Navigation Guidance of spinal surgical instruments may rely on intraoperative 3D image plan using an optical system (infrared camera).	Stereotactic Instrument Navigation Guidance of spine surgical instrument based on an intra-operative plan developed with three-dimensional imaging software which is based on intraoperative 3D images using an optical system (infrared camera)	Stereotactic Freehand Navigation Guidance of spinal surgical instruments based on intraoperative 3D image using an optical system (infrared camera).	SUBSTANTIALLY EQUIVALENT to both predicates
Surgical flow in Instrument Navigation mode	- Patient Preparation and device installation - Intraoperative 3D image acquisition - Registration - Navigation for pilot hole preparation - Navigation of Third-party compatible instruments - Placement of spinal bone screws	- Patient preparation and device installation - Intraoperative 3D image acquisition - Registration - Intraoperative planning - Third-Party Instrument navigation for screw implantation	- Patient preparation and device installation - Intraoperative 3D image acquisition - Registration - Navigation - Placement of spinal implants (screws and interbody fusion devices)	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Surgical flow in Robotic-Assisted Guidance mode	- Patient Preparation and device installation - Intraoperative 3D image acquisition - Registration - -Landmark Check - Intraoperative planning - Instruments-holder positioning - Robotic-Assisted Guidance for pilot hole preparation - Robotic-Assisted Guidance of Third-Party compatible instruments - Placement of spinal bone screws	- Patient Preparation and device installation - Intraoperative 3D image acquisition - Registration - Landmark check - Intraoperative planning - Instruments-holder positioning - Pilot hole preparation	- Patient Preparation and device installation - Intraoperative 3D image acquisition - Registration - Landmark check - Intraoperative planning - Instruments-holder positioning - Robotic-Assisted Guidance of Third-Party compatible instruments - Placement of spinal screws	SUBSTANTIALLY EQUIVALENT to both predicates.
Registration Method	Automatic Intraoperative Registration	Automatic Intraoperative Registration	Automatic Intraoperative Registration	IDENTICAL to both predicates
Supported Image type	3D intra-operative CT exam	3D intra-operative CT exam	3D intra-operative CT exam	IDENTICAL to both predicates
DICOM compatibility	Yes	Yes	Yes	IDENTICAL to both predicates
Robotic Arm Dynamic compensation feature	Yes	Yes	Yes	IDENTICAL to both predicates
User's Control	The robot arm will only move if: - the user' hand continuously presses the activation buttons on the hand-grip of the Cobot (robotic arm), or - the user' foot continuously presses down the handsfree system (footswitch)	The robot arm will only move if: - the user' hand continuously presses the activation buttons on the hand-grip of the Cobot (robotic arm), or - the user's foot continuously presses down the handsfree system (footswitch)	The Robotic Arm motions during the surgery require continuous activation of the manual actuators or the hands-free actuator (footswitch).	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Robotic Alignment	Robotic alignment on the planned target defined by user during intra-operative planning. The Op.n™ CoBot moves is allowed only with user's action on robot hand-grip or footswitch.	Robotic alignment on the planned target defined by user during intra-operative planning. The Robot moves is allowed only with user's action on robot hand-grip or footswitch.	Robotic alignment on the planned target defined by user during intra-operative planning. The Robot moves is allowed only with user's action on robot hand-grip or footswitch.	IDENTICAL to both predicates
Graphical User Interface	System Specific GUI	System Specific GUI	System Specific GUI	IDENTICAL to both predicates
Device Accuracy in Instrument Navigation mode	Measurement of mean error between a positioning provided by the device and an actual positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	Measurement of mean error between a target positioning and a reached positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	Measurement of mean error between a positioning provided by the device and an actual positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	SUBSTANTIALLY EQUIVALENT to both predicates
Device Accuracy in Robotic-Assisted Guidance mode	Measurement of mean error between a planned positioning and a reached positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	Measurement of mean error between a planned positioning and a reached positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	Measurement of mean error between a planned positioning and a reached positioning: - Mean position error < 2 mm - Mean angular error < 2 degrees	IDENTICAL to both predicates
System Components				
Main System Components	**Op.n™ Spine Navigation and Robotic Guidance** is composed of the following main components: - Station - Dedicated software - Robotic arm - Navigation camera - Instruments for patient tracking - Instruments to enable navigation of compatible Third-Party instruments - Instruments for Robotic guidance	Op.n™ Navigation is composed of the following main components: - Station - Dedicated software - Robotic arm - Navigation camera - Instruments for patient tracking - Instruments to enable navigation of compatible Third-Party instruments - Instruments for Robotic guidance	Spine Navigation and Robotic-Assistance Device is composed of the following main elements: - Navigation station - Camera station - Robotic-Assisted station - Dedicated software - Dedicated Tracking system instrumentation	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Stations	**Op.n™ Core Station** - Two display monitors (Master monitor and Workflow Monitor) - Computer unit - ID card reader - Power supply	**Op.n™ Core** - Two display monitors (Master monitor and Workflow Monitor) - Computer unit - ID card reader - Power supply	**Navigation Station:** - Computer unit - Display touchscreen monitor - Power supply	SUBSTANTIALLY EQUIVALENT to both predicates
	Op.n™ Camera - Infrared camera - Arm - Casters The Op.n™ Camera supports the localization of navigation instruments for guided surgery procedures and communicates it to the Op.n™ Core Station.	**Op.n™ Camera** - Infrared camera - Arm - Casters The Op.n™ Camera supports the localization of navigation instruments for guided surgery procedures and communicates it to the Op.n™ Core.	**Camera Station:** - Infrared camera - Positioning Handle - Arm - Casters The Camera Station supports the localization of navigation instruments for guided surgery procedures and communicates it to the Navigation station.	SUBSTANTIALLY EQUIVALENT to both predicates
	Op.n™ CoBot - Robotic Arm - Control box for the robotic arm - Power supply - Footswitch	**CoBot** - Robotic Arm - Control box for the robotic arm - Power supply - Footswitch	**Robotic-Assisted Station:** - Robotic Arm with Tool Holder (end effector) - Robot Arm Controller - Human Machine Interface - Connectors Panel - Casters and stabilizers - Footswitch - Touchscreen monitor	SUBSTANTIALLY EQUIVALENT to Op.n Navigation SUBSTANTIALLY EQUIVALENT to Spine Navigation and Robotic-Assistance Device except for power supply: the Subject Device is directly linked to the power supply.

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Robotic Arm	- Guides spine instruments during general spine surgery - Instruments are mounted onto the robot arm's flange - Uses seven degrees of freedom architecture to guide instruments - Uses foot pedal and/or manual buttons for automatic alignment and cooperative mode - Has light indicators that reflect the status of the robotic-assisted guidance	- Guides spine instruments during general spine surgery - Instruments are mounted onto the robot arm's flange - Uses seven degrees of freedom architecture to guide instruments - Uses foot pedal and/or manual buttons for automatic alignment and cooperative mode - Has light indicators that reflect the status of the robotic-assisted guidance	- Guides spinal instruments at the desired trajectory - At the distal part of the Robotic Arm a Tool Holder (end-effector) is mounted to guide surgical instruments - Seven degrees of freedom - Use of Footswitch and/or manual actuators for motions (Handguiding, Alignment and Dynamic compensation modes) - Light Indicators that reflect the status of the Robotic-Assisted Guidance	SUBSTANTIALLY EQUIVALENT to both predicates
Dedicated Software	Dedicated interactive software application, which provides the functions needed to conduct the indicated spine procedures. The software application implements the methods for patient registration, planning screws' positions and then instrument guidance for preparation of pilot holes. The software interfaces with third-party surgical instruments to navigate them for placement of the spinal bone screw. Perla by Spineart: 1.0.0.260107171601	Dedicated interactive software application, which provides the functions needed to conduct the indicated spine procedures. The software application implements the methods for patient registration, planning screw positions and then instrument guidance for preparation of pilot holes. Op.n Perla TL Nav: 1.1.1.241030200302	Dedicated application software, used for intraoperative planning and visual guidance (Freehand Navigation and Robotic-Assisted Guidance) of surgical instruments.	SUBSTANTIALLY EQUIVALENT to both predicates
Optical Localizer	An infrared camera detects reflective markers to track the position of the robotic arm and instruments	An infrared camera detects reflective markers to track the position of the robotic arm and instruments	Infrared camera detects markers to track the position of the tracking system components. The device includes both passive and active markers (on the Robotic Arm).	SUBSTANTIALLY EQUIVALENT to both predicates

	Subject device: **Op.n™ Spine Navigation and Robotic Guidance**	Op.n™ Navigation	Spine Navigation and Robotic-Assistance Device	Discussion on Equivalence
Compatible Third-Party Instruments	Third-Party compatible instruments (Tap, screwdriver, drill, and pedicle probe) used in instrument navigation and/or robotic guidance mode. The list of compatible instruments can be found in Table 1 below.	Third-Party compatible instruments (tap & screwdriver) used in instrument navigation mode. The list of compatible instruments can be found in Table 1 below.	Third-Party compatible instruments (Tap, screwdriver, drill) used in instrument navigation and/or robotic guidance mode	SUBSTANTIALLY EQUIVALENT to Spine Navigation and Robotic-Assistance Device SUBSTANTIALLY EQUIVALENT to Op.n Navigation for instrument navigation mode.
Imaging system	Compatible with 3D imaging systems from Third-Party and eCential Robotics : - Vision FD Vario 3D (ZIEHM) - OEC 3D (General Electric) - O-Arm (Medtronic) - CIOS Spin Mobile 3D (Siemens) - SURGIVISIO (eCential Robotics)	Compatible with 3D imaging systems from Third-Party and eCential Robotics : - Vision FD Vario 3D (ZIEHM) - OEC 3D (General Electric) - O-Arm (Medtronic) - SURGIVISIO (eCential Robotics)	Compatible with 3D imaging Systems from Third-Party and eCential Robotics : - Vision FD Vario 3D (ZIEHM) - CIOS Spin Mobile 3D (Siemens) - Airo TruCT (Stryker) - OEC 3D (General Electric) - O-Arm (Medtronic) - SURGIVISIO (eCential Robotics)	SUBSTANTIALLY EQUIVALENT to Spine Navigation and Robotic-Assistance Device
Performance and Safety testing				
Performance & Safety Testing	Performed tests related to : - Hardware testing - Electrical Safety testing - Electromagnetic Compatibility testing - Software Verification & Validation activities - Performance characteristics testing - Cadaveric testing - Simulated Use system validation - Biocompatibility evaluation - Labeling verification	Performed tests related to : - Hardware testing - Electrical Safety testing - Electromagnetic Compatibility testing - Software Verification & Validation activities - Performance characteristics testing - Cadaveric testing -Simulated Use system validation -Biocompatibility evaluation - Labeling verification	Performed tests related to : - Electrical Safety testing - Electromagnetic Compatibility testing - Software Verification and Validation - Simulated use - Performance characteristics verification and validation - Biocompatibility testing - Labeling verification	SUBSTANTIALLY EQUIVALENT to both predicates
Labeling	FDA-recognized standards used for labeling verification	FDA-recognized standards used for labeling verification	FDA-recognized standards used for labeling verification	SUBSTANTIALLY EQUIVALENT to both predicates

Table 1: List of third-party compatible instruments in Subject Device and Predicate Device

Reference	Designation	Category	K number	Compatible with Subject Device	Compatible with Predicate device
NAV-IN 51 31-N	Nav. Drill Ø3.1	Drill	K261205	✓	
NAV-IN 50 00-N	Drill guide	Drill accessory	K261205	✓	
NAV-IN 50 31-N	Drill guide adjustable sleeve Ø3.1	Drill accessory	K261205	✓	
NAV-IN 50 10-N	Nav. Anti-rotation unit	Drill accessory	K261205	✓	
NAV-IN 11 50-N	Lumbo-Pelvic Nav. Probe Square Straight	Probe	K261205	✓	
AST-IN 10 40-N	Robotic Tap Ø4.0	Tap	K261205	✓	
AST-IN 10 45-N	Robotic Tap Ø4.5	Tap	K261205	✓	
AST-IN 10 50-N	Robotic Tap Ø5.0	Tap	K261205	✓	
AST-IN 10 55-N	Robotic Tap Ø5.5	Tap	K261205	✓	
AST-IN 10 60-N	Robotic Tap Ø6.0	Tap	K261205	✓	
AST-IN 10 65-N	Robotic Tap Ø6.5	Tap	K261205	✓	
AST-IN 10 70-N	Robotic Tap Ø7.0	Tap	K261205	✓	
AST-IN 10 80-N	Robotic Tap Ø8.0	Tap	K261205	✓	
AST-IN 10 90-N	Robotic Tap Ø9.0	Tap	K261205	✓	
AST-IN 10 10-N	Robotic Tap Ø10.0	Tap	K261205	✓	
AST-IN 30 10-N	Robotic Locking Screwdriver Shaft MS-PS	Screwdriver	K261205	✓	
AST-IN 30 30-N	Robotic Locking Screwdriver Shaft SS	Screwdriver	K261205	✓	
AST-IN 30 50-N	Robotic Locking Screwdriver Shaft XTAB	Screwdriver	K261205	✓	
AST-IN 30 00-N	Robotic Locking Screwdriver Tube	Screwdriver	K261205	✓	
NAV-IN 33 80-N	Perla TL Nav. Screwdriver, Universal, Non Cannulated	Screwdriver	K261205	✓	
NAV-IN 33 90-N	Perla TL Nav. Locking Screwdriver, MS-PS, Non Cannulated	Screwdriver	K261205	✓	
NAV-IN 32 40-N	Perla TL Nav. Tap Ø4.0	Tap	K242890	✓	✓
NAV-IN 32 45-N	Perla TL Nav. Tap Ø4.5	Tap	K242890	✓	✓

Reference	Designation	Category	K number	Compatible with Subject Device	Compatible with Predicate device
NAV-IN 32 50-N	Perla TL Nav. Tap Ø5.0	Tap	K242890	✓	✓
NAV-IN 32 55-N	Perla TL Nav. Tap Ø5.5	Tap	K242890	✓	✓
NAV-IN 32 60-N	Perla TL Nav. Tap Ø6.0	Tap	K242890	✓	✓
NAV-IN 32 65-N	Perla TL Nav. Tap Ø6.5	Tap	K242890	✓	✓
NAV-IN 32 70-N	Perla TL Nav. Tap Ø7.0	Tap	K242890	✓	✓
NAV-IN 32 75-N	Perla TL Nav. Tap Ø7.5	Tap	K242890	✓	✓
NAV-IN 32 80-N	Perla TL Nav. Tap Ø8.0	Tap	K242890	✓	✓
NAV-IN 32 85-N	Perla TL Nav. Tap Ø8.5	Tap	K242890	✓	✓
NAV-IN 32 90-N	Perla TL Nav. Tap Ø9.0	Tap	K242890	✓	✓
NAV-IN 32 95-N	Perla TL Nav. Tap Ø9.5	Tap	K242890	✓	✓
NAV-IN 32 10-N	Perla TL Nav. Tap Ø10.0	Tap	K242890	✓	✓
NAV-IN 32 15-N	Perla TL Nav. Tap Ø10.5	Tap	K242890	✓	✓
NAV-IN 34 45-N	Perla TL Nav. Cortical Tap Ø4.5	Tap	K242890	✓	✓
NAV-IN 34 50-N	Perla TL Nav. Cortical Tap Ø5.0	Tap	K242890	✓	✓
NAV-IN 34 55-N	Perla TL Nav. Cortical Tap Ø5.5	Tap	K242890	✓	✓
NAV-IN 34 60-N	Perla TL Nav. Cortical Tap Ø6.0	Tap	K242890	✓	✓
NAV-IN 34 65-N	Perla TL Nav. Cortical Tap Ø6.5	Tap	K242890	✓	✓
NAV-IN 34 70-N	Perla TL Nav. Cortical Tap Ø7.0	Tap	K242890	✓	✓
NAV-IN 34 75-N	Perla TL Nav. Cortical Tap Ø7.5	Tap	K242890	✓	✓
NAV-IN 36 50-N	Perla TL Nav. Cannulated Tap Ø5.0	Tap	K242890	✓	✓
NAV-IN 36 55-N	Perla TL Nav. Cannulated Tap Ø5.5	Tap	K242890	✓	✓
NAV-IN 36 60-N	Perla TL Nav. Cannulated Tap Ø6.0	Tap	K242890	✓	✓
NAV-IN 36 65-N	Perla TL Nav. Cannulated Tap Ø6.5	Tap	K242890	✓	✓
NAV-IN 36 70-N	Perla TL Nav. Cannulated Tap Ø7.0	Tap	K242890	✓	✓
NAV-IN 36 75-N	Perla TL Nav. Cannulated Tap Ø7.5	Tap	K242890	✓	✓

Reference	Designation	Category	K number	Compatible with Subject Device	Compatible with Predicate device
NAV-IN 36 80-N	Perla TL Nav. Cannulated Tap Ø8.0	Tap	K242890	✓	✓
NAV-IN 36 85-N	Perla TL Nav. Cannulated Tap Ø8.5	Tap	K242890	✓	✓
NAV-IN 36 90-N	Perla TL Nav. Cannulated Tap Ø9.0	Tap	K242890	✓	✓
NAV-IN 36 95-N	Perla TL Nav. Cannulated Tap Ø9.5	Tap	K242890	✓	✓
NAV-IN 36 10-N	Perla TL Nav. Cannulated Tap Ø10.0	Tap	K242890	✓	✓
NAV-IN 36 15-N	Perla TL Nav. Cannulated Tap Ø10.5	Tap	K242890	✓	✓
NAV-IN 33 30-N	Perla TL Nav. Screwdriver MS-PS Cannulated	Screwdriver	K242890	✓	✓
NAV-IN 33 40-N	Perla TL Nav. Screwdriver SS	Screwdriver	K242890	✓	✓
NAV-IN 33 50-N	Perla TL Nav. Screwdriver Universal Cannulated	Screwdriver	K242890	✓	✓
NAV-IN 33 60-N	Perla TL Nav. Locking Screwdriver MS-PS Cannulated	Screwdriver	K242890	✓	✓
NAV-IN 33 70-N	Perla TL Nav. Locking Screwdriver SS	Screwdriver	K242890	✓	✓
NAV-IN 35 10-N	Perla TL Nav. Cortical Screwdriver Tube	Screwdriver	K242890	✓	✓
NAV-IN 35 20-N	Perla TL Nav. Cortical Screwdriver Shaft	Screwdriver	K242890	✓	✓
NAV-IN 37 20-N	Perla TL Nav. Locking Screwdriver XTAB	Screwdriver	K242890	✓	✓

Performance Data

Nonclinical tests:

The following nonclinical tests were performed on the **Op.n™ Spine Navigation and Robotic Guidance** to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

Design Verification

Design verification tests were performed based on risk management activities (conducted in accordance with ISO 14971 Third Edition 2019-12: Medical Devices – Application of risk management to medical devices) and product requirements.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility (EMC) testing were conducted in accordance with:

IEC 60601-1 Edition 3.2 2020-08 consolidated version: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance;

IEC 60601-1-2 Edition 4.1 2020-09 consolidated version: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests; and

IEC 80601-2-77 Edition 1.0 2019-07: Medical electrical equipment - Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT.

Usability

Usability was evaluated in accordance with:

IEC 60601-1-6 Edition 3.2 2020-07 consolidated version: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.

IEC 62366-1 Edition 1.1 2020-06 consolidated version: Medical devices - Part 1: Application of usability engineering to medical device and FDA guidance.

Software Verification and Validation Testing

Software development and testing activities were conducted in accordance with:

IEC 62304 Edition 1.1 2015-06 consolidated version: Medical device software – Life cycle processes and FDA guidance.

Accuracy Testing

Accuracy testing activities were conducted in accordance with:

ASTM F2554-22: Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.

A bench testing has been performed to assess positional accuracy of navigated surgical instrument, and

A cadaveric study has been performed to assess the accuracy and the safety of the device.

Reprocessing validation

Reprocessing activities were evaluated and testing in accordance with:

AAMI TIR12:2020/(R)2023: Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

ISO 17665 First edition 2024-03: Sterilization of health care products Moist heat : Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 17664-1 First Edition 2021-07: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices.

Biocompatibility Testing

Biological evaluation was evaluated and testing in accordance with:

ISO 10993-1 Fifth edition 2018-08: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;

ISO 10993-5 Third edition 2009-06-01: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;

ISO 10993-10 Fourth edition 2021-11: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;

ISO 10993-11 Third edition 2017-09: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity;

ISO 10993-17 Second edition 2023-09-01: Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances; and

ISO 10993-23 First edition 2021-01: Biological evaluation of medical devices - Part 23: Tests for irritation

Transport validation

Transport validation tests were performed in accordance with:

ASTM D4169-22 – Standard Practice for performance Testing of Shipping Containers and Systems

Design Validation

Op.n™ Spine Navigation and Robotic Guidance was validated with intended Users in simulated use testing to ensure the users' needs and intended use requirements were met.

Animal study:

Animal performance testing was not required to demonstrate safety and effectiveness.

Clinical tests:

No clinical tests were conducted to demonstrate substantial equivalence.

PCCP :

eCential Robotics has submitted a Predetermined Change Control Plan (PCCP), whose goal is to enable the modification of **Op.n™ Spine Navigation and Robotic Guidance** Software to support additional compatibility with instruments and implants legally-marketed by a Third-Party Manufacturer (Partner) solely by adding a new software configuration to the subject device, while maintaining the device's intended use, safety, and effectiveness.

The PCCP describes the planned change, and provides a modification protocol, implementation process, ensuring the device continues to meet substantial equivalence.

The discussed modification will follow the provisions described within the PCCP. Verification and validation activities will be conducted as planned to ensure continued performance of **Op.n™ Spine Navigation and Robotic Guidance**, including Software verification and accuracy verification and validation activities.

Table 2: Verification and validation activities and the respective defined acceptance criteria

#	Verification and validation activities	Acceptance Criteria/Requirements
1	Verify Budget Accuracy Specifications requirements	All new compatible instruments and implants meet the designated design requirements including identified specifications for: • Dimensions: minimum and maximum required length and diameter, • Connection: compatibility of partner's instrument with either ECENTIAL ROBOTICS' specific adapter or compatibility of partner's adapter with ECENTIAL ROBOTICS' Op.n Tracker.
2	Software configuration - Partner Database Compatibility Verification Test	The clinical application dedicated to the partner can be launched on the Op.n Core Station. The workflow can be performed up to the navigation step where any device from the associated database can be navigated.
3	Labeling Verification Test	All identified verification items are PASS.
4	Non-Clinical Bench Performance Testing - Accuracy & Safety Assessment Test in cadaveric specimens, performed by representative users.	Safety - *Pedicular breaches evaluation*: Non-inferiority is demonstrated if the observed good screw positioning rate ($p_{measured}$), as determined using Gertzbein-Robbins scale, is greater than or equal to the predefined expected threshold corresponding to the conventional method ($p_{expected}$ = 97%). - *Safe positioning* : Safety is demonstrated if the observed safe screw positioning rate ($p_{measured}$), as determined using the Zdichavsky grading scale, is greater than or equal to the

		predefined expected threshold corresponding to the conventional method ($p_{expected}$ = 98%). <u>Accuracy</u> The upper bound level of the 99% Confidence Interval for mean screw angle deviation is ≤ 2°. The upper bound level of the 99% Confidence Interval for mean screw tip-, middle, and head-distance deviation is ≤ 2mm. In Instrument navigation mode : the deviation is measured with respect to navigation (virtual implant) positioning. In Robotic guidance mode: the deviation is measure with respect to Intraoperative surgical planning positioning.
5	Change management: Long-term compatibility is ensured within an agreement between eCential Robotics and the Third-Party Manufacturer.	The agreement will include as a minimum, the following commitments: Each Party will provide the other Party with information about their respective Product changes and evolutions that may impact the Products, in accordance with reasonable industry practices. The Parties shall make reasonable best efforts to assist the other Party in managing the impact of changes.

The modification will be implemented only if the V&V results meet the defined acceptance criteria. If verification & validations activities are not successful, then the modification is not implemented - meaning the Op.n™ Spine Navigation and Robotic Guidance will not claim compatibility to the additional Third-Party Manufacturer's devices.

Users are informed about the implemented modification through updated labeling, including dedicated user manuals, identifying the configuration name, software versions, quoting the list of all compatible devices and the related commercial reference of the Op.n™ Spine Navigation and Robotic Guidance software.

Conclusions drawn from Performance Data

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR 807, and based upon the information and scientifically valid data provided in this premarket notification, eCential Robotics concludes that the subject device, the **Op.n™ Spine Navigation and Robotic Guidance** is as safe and effective and performs as well as the predicate devices, the Op.n™ Navigation and to the Spine Navigation and Robotic-Assistance Device. Substantial equivalence was established in terms of design features, technological characteristics, intended use and performance as compared to the two predicate devices.

Performance and Safety Testing activities have demonstrated that **Op.n™ Spine Navigation and Robotic Guidance** does not raise any question of safety or effectiveness.

Regarding the Performance and safety testing, **Op.n™ Spine Navigation and Robotic Guidance**, Op.n™ Navigation (K242914) and Spine Navigation and Robotic-Assistance Device (K233228) are substantially equivalent.

A Predetermined Change Control Plan (PCCP) is included to outline post-clearance modifications and their evaluation. The planned change includes an impact assessment and test plan to ensure continued safety, effectiveness, and substantial equivalence to the predicate device.