December 15, 2025

Proprio, Inc.
Shannon Eubranks
Vice President, Systems Engineering and Regulatory
111 West John Street, Suite 308
Seattle, Washington 98119

Re: K252950
Trade/Device Name: Paradigm System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 15, 2025
Received: September 16, 2025

Dear Shannon Eubranks:

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

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.	K252950 ?

Please provide the device trade name(s). ?

Paradigm System

Please provide your Indications for Use below. ?

The Paradigm System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons during open surgical procedures with appropriate bone preparation. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure that can be identified on CT derived patient images for pedicle screw cannulation of the thoracic to sacrum vertebrae.

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

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

510(k) Summary Statement

Submitter:	Proprio, Inc.
Contact Person:	Shannon Eubanks VP of Systems Engineering and Regulatory Phone: (425) 802-6063 Email: seubanks@propriovision.com
Trade Name:	Paradigm System
Common Name:	Orthopedic stereotaxic instrument
Classification:	Class II
Product Code:	OLO
Regulation:	21 CFR 882.4560
Predicate Device(s):	The subject device is equivalent to the following device: Paradigm System (K250879)
Device Description:	The Paradigm System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons. The Paradigm system fuses high-resolution, real-time camera imaging of the surgical site (such as the spine) with medical imagery (such as CT) and surgical navigation data, such as predetermined instrument trajectories for precise instrument placement. The Paradigm System encompasses non-sterile operating room equipment components as well as sterilizable, reusable instruments, and off-the-shelf sterile-packaged, single-use accessories. The Paradigm System is used with an external monitor.
Indications For Use:	The Paradigm System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons during open surgical procedures with appropriate bone preparation. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure that can be identified on CT derived patient images for pedicle screw cannulation of the thoracic to sacrum vertebrae.

	Paradigm System (Subject Device)	Paradigm System (Predicate Device)	Comment
Device Overview			
510(k) Number Decision Date	K252950	K250879 June 4, 2025	
Manufacturer	Proprio, Inc.	Proprio, Inc.	Same
Classification	Class II	Class II	Same
Product Code	OLO	OLO	Same
Regulation	21 CFR 882.4560	21 CFR 882.4560	Same
Medical Specialty	Neurology	Neurology	Same
Indications for Use	The Paradigm System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons during open surgical procedures with appropriate bone preparation. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure that can be identified on CT derived patient images for pedicle screw cannulation of the thoracic to sacrum vertebrae.	The Paradigm System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons during open surgical procedures with appropriate bone preparation. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure that can be identified on CT derived patient images for pedicle screw cannulation of the thoracic to sacrum vertebrae.	Same
Principle of Operation	Paradigm System fuses high-resolution, real-time camera imaging of the surgical site (such as the spine) with medical imagery (such as CT) and surgical navigation data, such as predetermined instrument trajectories for precise instrument placement. The Paradigm System enables surgical navigation of instruments relative to the patient spinal anatomy by combining preoperative imaging segmentation and intraoperative registration of the patient's live anatomy. Preoperative CT data is uploaded to the console and the system software generates a 3D model of the patient's operative vertebrae. The 3D model is used for preoperative planning such as implant placements or instrument trajectories. During the procedure, once the patient's anatomy is exposed, the Prism Sensor Array acquires imaging to match the topography of the live anatomy to the 3D model.	Paradigm System fuses high-resolution, real-time camera imaging of the surgical site (such as the spine) with medical imagery (such as CT) and surgical navigation data, such as predetermined instrument trajectories for precise instrument placement. The Paradigm System enables surgical navigation of instruments relative to the patient spinal anatomy by combining preoperative imaging segmentation and intraoperative registration of the patient's live anatomy. Preoperative CT data is uploaded to the console and the system software generates a 3D model of the patient's operative vertebrae. The 3D model is used for preoperative planning such as implant placements or instrument trajectories. During the procedure, once the patient's anatomy is exposed, the Prism Sensor Array acquires imaging to match the topography of the live anatomy to the 3D model.	Registration initialized by tracing vertebral landmarks of exposed bone added. Point cloud representation changed from green to blue.

	Registration is initialized by point matching on the vertebra or by tracing vertebral landmarks of exposed bone. This intraoperative registration of live anatomy to the 3D model creates a common coordinate space between the preoperative CT data and the patient anatomy represented as a blue point cloud. This enables virtual information to be overlaid on the live anatomy during the procedure for intraoperative guidance.	Registration is initialized by point matching on the vertebra. This intraoperative registration of live anatomy to the 3D model creates a common coordinate space between the preoperative CT data and the patient anatomy represented as a green point cloud. This enables virtual information to be overlaid on the live anatomy during the procedure for intraoperative guidance.	
Technical Comparison	Stereotaxic image guided surgical navigation system during spine surgery. Preoperative CT data is segmented and a 3D model is generated. Preoperative planning can be performed. Intraoperative image capture using reflective markers on spinal instruments and registers the patient's anatomy to the preoperative 3D model for intraoperative guidance during the procedure.	Stereotaxic image guided surgical navigation system during spine surgery. Preoperative CT data is segmented and a 3D model is generated. Preoperative planning can be performed. Intraoperative image capture using reflective markers on spinal instruments and registers the patient's anatomy to the preoperative 3D model for intraoperative guidance during the procedure.	Same
Components	Cart, Arm, Sensor Array, External Monitor, Foot switch, Surgical Instruments, Software	Cart, Arm, Sensor Array, External Monitor, Surgical Instruments, Software	Foot switch added
Energy Source	120V	120V	Same
Sterilization Method – Surgical Instruments	Steam	Steam	Same
Minimum SAL	1×10^{-6}	1×10^{-6}	Same
Required Accessories	Reflective Markers (Northern Digital K033621)	Reflective Markers (Northern Digital K033621)	Same
Optional Accessories	Paradigm Drape	Paradigm Drape	Same
Sterilization Method – Drape	Ethylene Oxide	Ethylene Oxide	Same
Minimum SAL	1×10^{-6}	1×10^{-6}	Same
<u>Functional and Safety Testing:</u>	Verification and Validation activities have been conducted to provide assurance that the device meets the performance requirements under the indications for use conditions. Proprio performed the following testing to ensure the safety and effectiveness of the Paradigm System device: • Non-clinical Hardware and Software Verification Tests • Non-clinical Design Validation conducted in Cadaveric Model • Compliance Conformity Assessments The following standards were used in testing: • IEC 60601-1:2005/AMD1:2012 and AMD2:2020 Medical electrical equipment. General requirements for basic safety and essential performance.		

	• IEC 60601-1-2:2014+ AMD:1 2020 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility • IEC TS 60601-4-2:2024 Medical Electrical Equipment – Part 4-2, Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems • IEC 60601-1-6:2010/AMD1:2013 and AMD2:2020 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability • IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements • IEC 62366-1: 2015/AMD1:2020 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices, including Amendment 1 • ISO 14971:2019 Medical devices – Application of risk management to medical devices • IEC 62304 Edition 1.1 2015-06 Medical device software – Software life cycle processes
Conclusion:	The Paradigm System intended use, indications for use, and fundamental scientific technology is the same as the predicate device. Performance, safety and usability testing demonstrate that the differences between the subject device and the predicate device do not raise new risks of safety and effectiveness.