April 21, 2023

Proprio, Inc.
Shannon Eubanks
Vice President, HW Engineering and Regulatory
111 W John Street
Suite 308
Seattle, Washington 98119

Re: K222291
Trade/Device Name: Paradigm System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 20, 2023
Received: March 22, 2023

Dear Shannon Eubanks:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222291

Device Name
Paradigm System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.0 510(k) Summary/Statement

Table 1: 510(k) Summary

Submitter:	Proprio, Inc
Contact Person:	Shannon Eubanks VP of HW Engineering and Regulatory Phone: (425) 802-6063 E-mail: seubanks@propriovision.com
Trade Name:	Paradigm System
Common Name:	Orthopedic stereotaxic instrument
Classification:	Class II
Product Code:	OLO
Regulation	21 CFR 882.4650
Predicate Device(s):	The subject device is equivalent to the following device: Envision 3D™: Image Guidance System (K162375)
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.
Indication 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)	Envision 3D™: Image Guidance System (Predicate Device)	Comment
Device Overview			
510(k) Number Decision Date	To be determined	K162375 December 29, 2016	
Manufacturer	Proprio, Inc	7D Surgical, Inc	
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 Envision 3D™: Image Guidance System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The system is also intended to be used as the primary surgical luminaire during image guided surgery. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure can be identified.	Subject device is not the primary luminaire.

	Paradigm System (Subject Device)	Envision 3D™: Image Guidance System (Predicate Device)	Comment
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. This intraoperative registration of live anatomy to the 3D model creates a common coordinate space between the preoperative CT data and the patient anatomy. This enables virtual information to be overlaid on the live anatomy during the procedure for intraoperative guidance.	The Envision 3D system provides image registration between preoperative scan data and data captured intraoperatively from the Envision 3D™ integrated structured light scanner and/or user selected points. The system provides guidance data by displaying the locations of wireless optically tracked Envision 3D™ Spinal Instruments (examples include pedicle probe and awl) relative to the patient. Position and orientation data of tracked Envision 3D™ Spinal Instruments are linked to the preoperative scan data using the Envision 3D™ workstation.	Subject device uses light field where predicate uses structured light scanner. Subject device segments each vertebra where the predicate as if it were a single anatomical body.
Technical Comparison	Stereotaxic image guided surgical navigation system during spine	Stereotaxic image guided surgical navigation system	Subject device has option for

	Paradigm System (Subject Device)	Envision 3D™: Image Guidance System (Predicate Device)	Comment
	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.	during spine surgery. Preoperative CT data is loaded onto the cart. Intraoperative registration of the patient's anatomy with the preloaded CT data using 3D structured light images. Reflective markers on spinal instruments aid the surgeon in viewing the position and orientation of instruments relative to registered pre-operative image data while performing the surgical procedure.	preoperative planning.
Components	Cart, Arm, Sensor Array, External Monitor, Surgical Instruments, Software	Cart, Arm, Head, tracked surgical Envision 3D™ Spinal Instruments, Software	Same.
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	Same

Functional and Safety Testing:	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, Software, and Instrumentation Verification Tests • Non-Clinical Design Validation conducted in Cadaveric Model • Cadaveric Simulated Workflow Study Assessing Usability • Compliance Conformity Assessments The following standards were used in testing: • IEC 60601-1:2015 Medical electrical equipment. General requirements for basic safety and essential performance • IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility • IEC 60601-1-6:2010+AMD1:2013 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 Ed1Medical Devices – Part 1: Application of Usability Engineering To Medical Devices • ISO 10993-1:2003 Biological evaluation of medical devices: Part 1: Evaluation and testing • ISO 14971:2019 Medical devices – Application of risk management to medical devices • ISO 17665-1:2006 Sterilization of health care products – Moist heat – Part:1 Requirements for the development, validation and routine control of a sterilization process for medical device • AAMI / ANSI ST79:2017 Guide to Steam Sterilization • ASTM F2554-18 Standard Practice For Measurement Of Positional Accuracy Of Computer Assisted Surgical Systems
Conclusion:	The Paradigm System intended use, indications for use, and fundamental scientific technology is similar to 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.