September 5, 2025

inTRAvent Medical Partners
℅ Connie Qiu
Senior Medical Technology Regulatory Consultant
ProPharma MedTech
107 West Hargett St.
Raleigh, North Carolina 27601

Re: K251317
Trade/Device Name: SOLOPASS 2.0 System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, IYN
Dated: April 29, 2025
Received: August 11, 2025

Dear Connie Qiu:

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,

Yen-chih Lin -S

Digitally signed by Yen-chih Lin -S
Date: 2025.09.05 14:29:54 -04'00'

For
Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251317

Device Name

SOLOPASS® 2.0 System

Indications for Use *(Describe)*

The SOLOPASS 2.0 System is a tool that obtains ultrasound images and positional data to provide intra-procedural, image guided localization and navigation, to aid in the frontal placement of an intra-ventricular catheter.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary - K251317

Sponsor: inTRAvent Medical Partners, LP
1730 Walton Road, Suite 110
Blue Bell, PA 19422

Contact: Connie Qiu
ProPharma MedTech
107 West Hargett St.
Raleigh, NC 27601

Date Prepared: August 27, 2025

Trade Name: SOLOPASS® 2.0 System

Common Name: Neurological stereotaxic instrument

Classification: II

Product Code:

(Primary) HAW, 21 CFR 882.4560, Neurological Stereotaxic Instrument

IYN, 21 CFR 892.1550, System, Imaging, Pulsed Doppler, Ultrasonic

Predicate Device: SOLOPASS® System (K203251)

Description of Device:

The SOLOPASS® 2.0 System is the next generation product of the predicate device, SOLOPASS® System. The subject device maintains the same indications for use and operating principles as the predicate device.

The SOLOPASS® 2.0 System is a neuronavigational system that collects intraoperative ultrasound imaging referenced to a skull mounted fixation device, allowing the user to plan the desired placement for external ventricular drain (EVD). The system utilizes two-dimensional imaging data with simultaneously captured location data to build a three-dimensional model of the anatomy without the use of preoperative imaging. Once the user has chosen a catheter placement location, the fixation device is locked in place to guide a catheter towards the intended anatomic location.

The SOLOPASS® 2.0 System consists of three main sub-systems:

1. The Patient Interface Device (PID): A skull-mounted fixation device that translates mechanical motion into digital position and secures the Ultrasound Probe and Catheter Guide.
2. The Ultrasound Probe "The Probe": A custom cranial "burr-hole" style probe used to collect intraoperative ultrasound image data from the patient.
3. The Workstation: A custom, portable unit that includes a dedicated operating system, imaging software application, and 27" monitor for displaying the User Interface. The Workstation is the primary interface of the other subsystems and is controlled by the included foot pedal.

Indications for Use:

The SOLOPASS® 2.0 System is a tool that obtains ultrasound images and positional data to provide intra-procedural, image guided localization and navigation, to aid in the frontal placement of an intraventricular catheter.

Comparison to Predicate Device:

Comparison of intended use and technological characteristics between the SOLOPASS® 2.0 System to the predicate device, SOLOPASS® System K203251 is presented below.

Table 1 Comparison of Subject and Predicate Devices

	Subject Device SOLOPASS® 2.0 System	**Predicate Device SOLOPASS® System**	**Substantial Equivalence Comparison**
Product Codes	HAW, IYN	HAW, IYN	Same
Indications for Use	The SOLOPASS® 2.0 system is a tool that obtains ultrasound images and positional data to provide intra-procedural, image guided localization and navigation, to aid in the frontal placement of an intraventricular catheter.	The SOLOPASS® system is a tool that obtains ultrasound images and positional data to provide intra-procedural, image guided localization and navigation, to aid in the frontal placement of an intraventricular catheter.	Same
Planned Use Environment	Operating Room (OR), Patient Bedside outside of OR	Operating Room (OR), Patient Bedside outside of OR	Same
Planned User	Surgeon or qualified HCP	Surgeon or qualified HCP	Same
Anatomic region	Cranial	Cranial	Same

Use For Neurosurgical Catheter/ Instrument Placement	Yes	Yes	Same
Main System Components	Ultrasound Imaging System; Skull mounted mechanical module; Software Module for trajectory planning; Workstation/ Display; Cart.	Ultrasound Imaging System; Skull mounted mechanical module; Software Module for trajectory planning; Workstation/ Display; Cart.	Same
Image Guidance	Ultrasound Intra-op 2D imaging data with simultaneously captured location data is used to build 3D model of anatomy	Ultrasound Intra-op 2D imaging data with simultaneously captured location data is used to build 3D model of anatomy	Same
Trajectory Guide Function	Yes	Yes	Same
Patient Fixation	Skull-mounted frame (Patient Interface Device, PID) serves as reference for instruments and catheters	Skull-mounted frame (Patient Interface Device, PID) serves as reference for instruments and catheters	Same
Manually Operated	Yes	Yes	Same
Instrument/ Catheter Compatibility	Catheters with 3.4mm or 2.8mm outer diameter	Catheters with 3.4mm or 2.8mm outer diameter	Same
Localization Method	Encoders on Patient Interface Device to track motion of instruments/ catheters	Encoders on Patient Interface Device to track motion of instruments/ catheters	Same
Transducer Type	Phased Array Probe	Phased Array Probe	Same
Transducer Frequency	5 Mhz 1 Transducer	5 Mhz 1 Transducer	Same
Transducer Style	“Burr-Hole” Style (Craniotomy)	“Burr-Hole” Style (Craniotomy)	Same
Acoustic Output Display & FDA Limits	Track 3	Track 3	Same
Imaging Mode	B Mode	B Mode	Same

General Safety and Effectiveness Information	1. Total Image Depth 0-9 cm 2. Optimal Image Range 2.5 – 8 cm	1. Total Image Depth 0-10 cm 2. Optimal Image Range 2.5 – 8 cm	Similar. Total image depth was reduced by 1cm to enlarge useful area shown on screen.
Accuracy	Targeting Accuracy: +/- 2mm Imaging Accuracy: +/- 1.5mm	Targeting Accuracy: +/- 3mm Imaging Accuracy: +/- 2mm	Targeting Accuracy improved from +/-3mm to +/-2mm. Imaging Accuracy improved from +/-2mm to +/-1.5mm
User Interfaces	Graphical Touch Screen, Foot Switch	Graphical Touch Screen, Foot Switch	Same
Electrical Safety	Conformity to IEC 60601-1 IEC 60601-2	Conformity to IEC 60601-1 IEC 60601-2	Same
Biocompatibility Patient Contacting Components	Conformity To ISO 10993-1 Limited Contact (<24 Hours) • Patient Interface Device • Ultrasonic Probe Used With Sheath And Acoustic Gel	Conformity To ISO 10993-1 Limited Contact (<24 Hours) • Patient Interface Device • Ultrasonic Probe Used With Sheath And Acoustic Gel	Same
Sterilization	PID: Sterile, single-use, Gamma Ultrasound Probe: Reusable, sterilized by vapor hydrogen peroxide (VHP) by the end user	PID: Sterile, single-use, Gamma Ultrasound Probe: Reusable, sterilized by vapor hydrogen peroxide (VHP) by the end user	Same

Nonclinical Testing Summary:

The following performance data are provided in support of the substantial equivalence determination between the proposed device, SOLOPASS® 2.0 System to the first-generation predicate device, SOLOPASS® System K203251.

Table 2 Summary of Non-Clinical Performance Data

TEST	TITLE/TEST METHOD SUMMARY	RESULTS
Biocompatibility		
ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic

ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-sensitizing Non-irritating
ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Non-pyrogenic Negative for acute systemic toxicity
ANSI/AAMI ST72, USP <85>, USP <161>	Bacterial endotoxins test	Pass, all samples demonstrated less than 2.15 Eu/device required for devices with cerebrospinal fluid contact
Thermal, Electrical, Mechanical Safety		
IEC 60601-1/ ANSI AAM ES 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral	Pass
IEC 60601-2-37	Particular Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.	Pass
AIM 7351731	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers	Pass
IEC/EN 60529	Degrees of protection provided by enclosures (PIX2, IPX7)	Pass
Cleaning, Disinfection, Sterilization		
Ultrasound Probe Cleaning Validation	Validation of cleaning and disinfection method for reusable ultrasound probes.	Pass
Ultrasound Probe VHP Sterilization Validation	Validation of VHP sterilization method for reusable ultrasound probes.	Pass, SAL 10^{-6}
AAMI/ANSI/ISO 11137-1, 11137-2	Validation of gamma sterilization method for single-use PID.	Pass, SAL 10^{-6}
Ship and Shelf Life Functional Test	Verify functional performance of device components following applicable testing per ISTA 3A, ISO 11607-1, and shelf-life aging.	Pass PID Shelf life: 12 months
Verification Bench Testing		
2D Imaging Qualification	Verification of ultrasound requirements including imaging depth, image accuracy, active element check and other specifications.	Pass
System Targeting Accuracy	Measure targeting accuracy. Acceptance criteria defined based on predicate device.	+/- 2.0mm target at 6cm
System Imaging Accuracy	Measure imaging accuracy.	+/- 1.5mm target at 6cm

Cranial Mounting Mechanical Testing	Verify performance of SOLOPASS® anchor assembly. Test methods based on ASTM F543.	Met acceptance criteria for: mean pullout strength of anchor.
Hardware Verification	Verify performance of system electrical design requirements in addition to electrical safety and EMC.	Pass
Software Verification and Validation		
Software Verification and Validation	Demonstrate that all software requirements were appropriately implemented in the software. Software development process demonstrates conformity to IEC 62304.	Pass
Design Validation		
Design validation study	Validation study in simulated use conditions to demonstrate that SOLOPASS® 2.0 System final design met user needs.	Pass, user needs were successfully validated

Conclusions:

In summary, the SOLOPASS® 2.0 System and predicate device, SOLOPASS® System (K203251), are substantially equivalent with respect to intended use and performance testing. Non-clinical testing results support that the subject and predicate devices are substantially equivalent in function for use as the predicate. The differences between the two devices do not raise new questions of safety and effectiveness.