August 27, 2021

inTRAvent Medical Partners, LP
℅ Connie Qiu
Regulatory Consultant
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York, New York 10001

Re: K203251
Trade/Device Name: SOLOPASS System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, IYN
Dated: December 3, 2020
Received: December 4, 2020

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203251

Device Name
SOLOPASS® System

Indications for Use *(Describe)*
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 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.

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510(k) Summary

Sponsor: inTRAvent Medical Partners, LP
1125 Greenwood Dr.
Hummelstown, PA 17036

Contact: Connie Qiu
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York, NY 10001

Date Prepared: August 27, 2021

Trade Name: SOLOPASS® System

Common Name: Neurological stereotaxic instrument

Classification: II

Product Code: HAW, 21 CFR 882.4560, Neurological Stereotaxic Instrument

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

Predicate Devices:

- Sonowand Invite System, K083597, K112469

Reference Devices

- Medtronic Navigus Trajectory Guide Kit, K992304
- V-Guide for Ventriculostomies K141559

Description of Device:

The SOLOPASS® 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. 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® 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.

The SOLOPASS® System provides 2mm Imaging Accuracy at 4-7cm depth and 3mm Targeting Accuracy at 6cm depth.

Indications for Use:

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 intra-ventricular catheter.

Comparison to Predicate Device:

Comparison of intended use and technological characteristics between the SOLOPASS® System to the predicate device, Sonowand Invite System (K083597, K112469), is presented in the following table. The differences between the two devices do not affect the intended use, and do not raise new questions of safety and effectiveness.

	Subject Device	**Predicate Device**	**Substantial Equivalence Comparison**
	SOLOPASS® System	SonoWand Invite™ K083597, K112469	N/A
Product Codes	HAW, IYN	HAW, IYN	Same
Indications for Use	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 intra-ventricular catheter.	The SonoWand Invite™ System is intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. It is also intended for use as a standard neuronavigation system and as a stand-alone Ultrasound scanner. The intended use of a localizer is to enable	Same intended use are tools used to assist the surgeon in planning and guiding the placement of instruments during neurosurgical procedures, such as catheter placement, with image guidance provided by ultrasound or other imaging modality. Predicate device has additional indications regarding other imaging modalities. These differences do not raise

		navigation by showing the position of surgical instruments or pointers relative to MR, CT, or Ultrasound images. The general purpose localizers with adapters are intended to be used to attach surgical tools manufactured by other vendors. SonoWand Invite™ System will display position and orientation of the tools in the medical images on the screen.	new questions of safety or effectiveness.
Planned Use Environment	Operating Room (OR), Patient Bedside outside of OR	Operating Room	Similar. Both devices are intended for use in the OR. The subject device is designed as a mobile workstation to allow for use at the patient bedside outside of the OR by qualified clinicians. While this adds a use environment, the intended use and qualifications of the intended users are equivalent to those of the predicate device. Electrical safety and electromagnetic compatibility testing using recognized test standards support the safety of the SOLOPASS as a mobile system. Therefore, these

			differences do not raise new questions of safety and effectiveness.
Planned User	Surgeon or intensivists	Surgeon	Similar. Typically this procedure is performed by HCP such as a surgeon or intensivist.
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; Not skull mounted (Localizer and Navigation Trackers on probe); Radiographic fiducial markers; Software module for instrument tracking; Workstation/ Display; Cart.	Similar. Both devices utilize an ultrasound imaging system with custom software module to aid in instrument (e.g. catheter) placement, and consist of a workstation with display on a cart. The subject device offers the benefit of intraoperative ultrasound images updated in real-time to facilitate trajectory planning and potentially reduce risks associated with targeting. There are differences in how each system helps track/guide placement of the instruments. Verification testing demonstrates that the subject device fulfills its design inputs including comparable accuracy to the predicate device. The differences between the main system components do not raise new questions of safety and effectiveness.

Image guidance	Ultrasound Intra-op 2D imaging data with simultaneously captured location data is used to build 3D model of anatomy	CT: Pre-op MRI: Pre-op Ultrasound: Intra-op (Intra-op MRI only available if MRI surgical suite available) Provides 2D and 3D imaging.	Both devices provide intra-op ultrasound imaging, and provide 2D and 3D imaging. The predicate device offers additional imaging modalities not offered by the subject device. This difference does not raise new questions of safety and effectiveness.
Trajectory guide function	Yes	Yes	Same
Patient fixation	Skull-mounted frame (Patient Interface Device, PID) serves as reference for instruments and catheters	No patient fixation component. Disposable radiographic markers are placed on or near craniotomy site.	Different. While the subject device includes a component that is fixed to the patient to guide placement of the ultrasound probe and instruments/ catheters, the predicate device does not have a patient fixation component. The two devices' designs utilize different methods of determining the patient's position for acquiring imaging and reference points. Bench testing of the SOLOPASS®. System verifies the PID design and performance to fulfill its intended use. These differences do not raise new questions of safety and effectiveness.
Manually operated	Yes	Yes	Same
Instrument/ Catheter compatibility	Catheters with 3.4mm or 2.8mm outer diameter	Does not specify limitation in instrument and/or catheter size compatibility	Different. The subject device specifies compatibility of instrument/ catheter sizes based on the design of

			the fixation component that limits the size of these devices. The predicate device does not have a similar component that would restrict the size of compatible instruments/ catheters. This difference does not impact the shared intended use and fundamental technology comparison between the subject and predicate devices. Performance testing verifies the compatible device sizes for the SOLOPASS®. Therefore, these differences do not raise new questions of safety and effectiveness.
Localization method	Encoders on Patient Interface Device to track motion of instruments/ catheters	Localizers with adapters that attach to instruments to track position. Adhesive radiographic markers placed near craniotomy site.	Similar. Both devices include components designed to track position of instruments/ catheters to aid in their placement to the surgical site during procedures. The differences between the localization methods do not raise new questions of safety and effectiveness.
Transducer Type	Phased array probe	Linear array probe, phased array probe	Same. Both systems offer phased array probes. The predicate device provides an additional linear array probe.
Transducer Frequency	5 MHz 1 transducer	5-10 MHz Multiple transducers available	Similar. 5 MHz transducer frequency is offered in both systems. Predicate device provides additional

			transducers with additional frequencies. These differences do not raise new questions of safety and effectiveness.
Transducer Style	"Burr-hole" style (craniotomy)	"Burr-hole" style (craniotomy)	Same
Acoustic Output Display & FDA Limits	Track 3	Unknown	The subject device met acoustic output testing acceptance criteria and FDA guidelines. Any differences in acoustic output display are not expected to raise new questions of safety and effectiveness.
Imaging Mode	B Mode	B Mode	Same
General Safety and Effectiveness Information	1. Total Image Depth 0-10 cm 2. Optimal Image Range 2.5 – 8 cm	1. Total Image Depth 0-9cm 2. Optimal Image Range 0-5 cm	Similar. Based on information about the predicate device available for comparison, both systems have similar parameters with some differences in range. Electrical safety, EMC, acoustic output, verification, and validation testing support the performance of the subject device, that these differences do not raise new questions of safety or effectiveness.
Accuracy	Targeting accuracy: +/- 3mm Imaging accuracy: +/- 2mm	Imaging accuracy: ±2mm[1]	Similar. The subject and predicate devices demonstrate similar imaging accuracy. SOLOPASS® has

[1] Lindseth, Frank et al. "Accuracy evaluation of a 3D ultrasound-based neuronavigation system." Computer aided surgery : official journal of the International Society for Computer Aided Surgery vol. 7,4 (2002): 197-222. doi:10.1002/igs.10046

			additionally been verified for targeting accuracy to aid the surgeon in placing instruments/ catheters. This does not raise new questions of safety and effectiveness.
User Interfaces	Graphical touch screen, Foot switch	Graphical touch screen, Foot switch	Similar. Any differences do not raise new questions of safety and effectiveness.
Electrical Safety	Conformity to IEC 60601-1 IEC 6060-1-2	Conformity to IEC 60601-1 IEC 6060-1-2	Same
Biocompatibility Patient Contacting Components	Conformity to ISO 10993-1 Limited contact (<24 hours) • Patient Interface Device (Anchor, etc.) • Ultrasonic probe used with sheath and acoustic gel	Conformity to ISO 10993-1 Limited contact (<24 hours) • Radiographic markers • Ultrasonic probe used with drape and acoustic gel	Similar. Both devices share common duration and type of intended tissue contact. Both devices satisfied applicable biocompatibility evaluation. Therefore, any differences in patient-contacting materials do not raise new questions of safety and effectiveness.
Sterilization	PID: Sterile, single-use, Gamma Ultrasound Probe: Reusable, sterilized by user by VHP	Spheres: Sterile, single-use Ultrasound Probe: Reusable, cannot be sterilized, must be used with sterile drape Localizers and navigators: Autoclave	Similar. Both devices have components delivered sterile or non-sterile, and have met applicable acceptance criteria for sterilization validation. Therefore, any differences in sterility methods do not raise new questions of safety and effectiveness.

Nonclinical Testing Summary:

The following performance data are provided in support of the substantial equivalence determination between the proposed device, SOLOPASS® System, and the predicate device, Sonowand Invite System (K083597, K112469).

Table 1 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 (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 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 Reference Device, V-Guide for Ventriculostomies (K141559).	+/- 3mm target at 6cm
System Imaging Accuracy	Measure imaging accuracy.	+/- 2mm target at 4cm-7cm
Cranial Mounting Mechanical Testing	Verify performance of SOLOPASS® screw and anchor compared to Reference Device Medtronic Navigus Trajectory Guide Kit (K992304). Test methods based on ASTM F543.	Met acceptance criteria for: mean pullout strength of anchor, mean ratio of yield strength vs. insertion torque.
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® final design met user needs.	Pass, user needs were successfully validated

Conclusions:

In summary, the SOLOPASS® System and predicate device, Sonowand Invite System (K083597, K112469), are substantially equivalent with respect to intended use. Non-clinical testing results support that the subject and predicate devices are substantially equivalent in function for use as neuro-navigation systems with intraoperative ultrasound imaging. The differences between the two devices do not raise new questions of safety and effectiveness.