March 17, 2023

Merit Medical Pte. Ltd.
Pauline Liow
Senior Regulatory Affairs Specialist
198 Yishun Avenue 7
Singapore, Singapore 768926

Re: K221782
Trade/Device Name: Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: June 16, 2022
Received: June 21, 2022

Dear Pauline Liow:

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,

Aneesh S. Deoras -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*

K221782

Device Name

Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes

Indications for Use *(Describe)*

The Meritrans ECO Reusable Pressure Transducer is intended to be coupled with a disposable dome kit for converting hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals for invasive blood pressure monitoring when connected to a patient monitor or recording device.

The devices are intended for pediatric and adult patient populations.

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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5.0 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Singapore Pte. Ltd.
	Address:	198 Yishun Avenue 7, Singapore 768926
	Telephone Number:	(65) 6750-9281
	Fax Number:	(65) 6754-3961
	Contact Person:	Ms. Pauline Liow
	Date Prepared:	June 16, 2022
	Establishment Registration: Number	8020616
Subject Device	Trade Name:	Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes
	Common/Usual Name:	Reusable Pressure Transducer
	Classification Name:	Transducer, Blood-Pressure, Extravascular
	Regulatory Class:	Class II
	Product Code:	DRS
	21 CFR §:	870.2850
	Review Panel:	Cardiovascular
Predicate Device	**Premarket Notification Predicate Device 1:**	
	Trade Name:	MX960 Reusable Pressure Transducer *(predicate for Meritrans ECO Reusable Pressure Transducer)*
	Common/Usual Name:	Reusable Pressure Transducer
	Classification Name:	Transducer, Blood-Pressure, Extravascular
	Premarket Notification:	K961404
	Manufacturer:	Smiths Medical ASD, Inc. (see *Note 1* below) **Note 1: The manufacturer, Medex, Inc. stated in the 510k letter, K961404 has been acquired by Smiths Medical.*
	Premarket Notification Predicate Device 2:	
	Trade Name:	LogiCal® Pressure Cartridges (disposable domes that are configured in the LogiCal® Transducer Pressure Monitoring System) *(predicate for Meritrans ECO Disposable Domes)*
	Common/Usual Name:	Reusable Pressure Transducer
	Classification Name:	Transducer, Blood-Pressure, Extravascular
	Premarket Notification:	K172458

	Manufacturer:	Smiths Medical ASD, Inc.
Classification	Regulatory Class:	II
	Product Code:	DRS
	21 CFR §:	21 CFR § 870.2850
	Review Panel:	Cardiovascular
Intended Use / Indications for Use	The Meritrans ECO Reusable Pressure Transducer is intended to be coupled with a disposable dome kit for converting hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals for invasive blood pressure monitoring when connected to a patient monitor or recording device. The devices are intended for pediatric and adult patient populations.	
Device Description	The Meritrans ECO Reusable Pressure Transducer is a non-invasive, reusable device used primarily for blood pressure monitoring. The housing assembly interfaces the pressure sensor assembly to the fluid channel of patient by coupling the transducer to the Meritrans ECO Disposable Dome. The fluid channel of patient is isolated from the pressure sensor by diaphragms. As the pressure signal of patient carried via the saline solution presses against the surface of transducer, the diaphragm is deflected, and the physiological pressure signal is transformed from the dome to the sensor of the reusable pressure transducer. Subsequently, the physiological pressure signal is transformed into electrical signal and displayed in a monitor that is connected via transducer interface cable. The Meritrans ECO Disposable Domes are disposable diaphragm domes which are coupled with the reusable transducer for invasive blood pressure monitoring. The disposable diaphragm dome has a transparent hemispherical hollow cavity. The domes have two ports; one port of the dome has a rotating Luer Lock fitting where the patient line is connected. Another port has an adaptor for connection to a pressurized IV fluid bag or an infusion pump. The disposable diaphragm dome has a diaphragm membrane that isolates the patient's fluid-filled system from the reusable transducer. For dome models with flush devices, an integral flow/flush device provides continuous flow of fluid to maintain catheter patency during the invasive blood pressure measurements.	
Comparison to Predicate Device	The subject Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes have the same intended use, principle of operation and design / technology concept as the predicate devices. Despite the slight differences in materials used or specifications, the safety and effectiveness of the devices are equivalent since they conform to the same FDA recognized standards such as ANSI/AAMI BP22 (*FDA Recognition Number: 3-44)*, IEC 60601-1-2 (*FDA Recognition Number: 19-36)*, IEC 60601-2-34 *(FDA Recognition Number: 3-115)*, IEC 62366-1 *(FDA Recognition Number: 5-129),* ISO 80369-7 *(FDA Recognition Number: 5-133)* and ISO 10993-1 *(FDA Recognition Number: 2-258)*. The subject devices are substantially equivalent to the predicate device 1 for transducer (K961404) and predicate device 2 for disposable domes (K172458).	

Safety & Performance Data	FDA guidance and FDA recognized / non-recognized consensus standards have been established for *Transducer, Blood-Pressure, Extravascular* under FDA 21 CFR § 870.2850 DRS. A battery of tests was performed based on the requirements of the below FDA recognized / non-recognized consensus standards and guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the subject Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes met the standards' established acceptance criteria applicable to the safety and effectiveness of the device. <u>Product Performances:</u> • ANSI/AAMI BP22:1994 (R)2016, Blood pressure transducers *[FDA Recognition Number: 3-44]* • IEC 60601-1:2020 (Edition 3.2), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2020 (Edition 4.1), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests *[FDA Recognition Number: 19-36]* • IEC 60601-2-34:2011 (Edition 3.0), Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment *[FDA Recognition Number: 3-115]* • IEC 62366-1:2015 + Cor 1:2016 + Amd 1:2020 [*Equivalent to IEC 62366-1:2020 (Edition 1.1 Consolidated Version)*], Medical devices - Part 1: Application of usability engineering to medical devices *[FDA Recognition Number: 5-129]* • ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications *[FDA Recognition Number: 5-133]* • FDA Guidance, Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, July 11, 2016 <u>Packaging and Transportation:</u> • EN ISO 2233:2001, Packaging - Complete, filled transport packages and unit loads - Conditioning for testing • ASTM D4169 - 16 (2016), Standard Practice for Performance Testing of Shipping Containers and Systems *[FDA Recognition Number: 14-499]* • EN ISO 11607-1:2020 (*Equivalent to ISO 11607-1:2019*), Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems *[FDA Recognition Number: 14-530]*

- ASTM F1980 - 16 (2016), Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices *[FDA Recognition Number: 14-497]*

Biocompatibility (for Meritrans ECO Disposable Domes):

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process *[FDA Recognition Number: 2-258]*
- ISO 10993-4:2017, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood *[FDA Recognition Number: 2-248]*
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity *[FDA Recognition Number: 2-245]*
- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity *[FDA Recognition Number: 2-255]*
- ISO 10993-12:2021 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials *[FDA Recognition Number: 2-289]*
- ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation *[FDA Recognition Number: 2-291]*
- FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 4, 2020

Sterilization / Sterility / EO residuals / Pyrogenicity (for Meritrans ECO Disposable Domes):

- EN ISO 11135:2014 (*Equivalent to ISO 11135:2014*) + Amd 1:2018 - Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and Routine Control of a sterilization process for medical devices *[FDA Recognition Number: 14-529]*
- EN ISO 10993-7:2008 + Cor 1:2009 + AMD 1:2019, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals *[FDA Recognition Number: 2-275]*
- AAMI TIR28:2016, Product Adoption and process equivalency for ethylene oxide sterilization
- ANSI/AAMI ST72:2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing *[FDA Recognition Number: 14-541]*
- United States Pharmacopeia 43, National Formulary 38:2020 (USP), General Chapter <151> Pyrogen Test
- FDA Guidance, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, January 21, 2016

Performance Bench Testing

The Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes comply with the FDA recognized / non-recognized consensus standards as outlined within this submission. Results of the testing demonstrate that the subject devices met the acceptance criteria sufficient for their intended use. The subject devices met the following requirements from these standards:

- Blood pressure transducers requirements per ANSI/AAMI BP22:1994 (R)2016
- General requirements for basic safety and essential performance of medical electrical equipment per IEC 60601-1:2020 (Edition 3.2)
- Requirements and tests relating to electromagnetic disturbances of Medical electrical equipment per IEC 60601-1-2:2020 (Edition 4.1)
- Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment per IEC 60601-2-34:2011 (Edition 3.0)
- Usability engineering requirements per IEC 62366-1:2015 + Cor 1:2016 + Amd 1:2020 [Equivalent to IEC 62366-1:2020 (Edition 1.1 Consolidated Version)]
- Requirements for connectors for intravascular or hypodermic applications per ISO 80369-7:2021

Biocompatibility testing

The biocompatibility evaluation for the Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes was conducted in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 4, 2020, and International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, as recognized by FDA. The reusable pressure transducer, Meritrans ECO Reusable Pressure Transducer does not come into contact directly or indirectly with the patient's body, tissues or fluid path, therefore testing per ISO 10993 is not required. As for the Meritrans ECO Disposable Domes, testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility

The Meritrans ECO Disposable Domes are externally communicating devices with blood path, indirect contact for a prolonged duration (> 24 hours to 30 days).

Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Meritrans ECO Reusable Pressure Transducer and Meritrans ECO Disposable Domes meet the requirements of all the applicable standards including the FDA recognized / non-recognized consensus standards that are considered essential for their intended use and are substantially equivalent to the predicate device 1 for transducer: MX960 Reusable Pressure Transducer, K961404 and predicate device 2 for disposable domes: LogiCal® Pressure Cartridges (*disposable domes that are configured in the LogiCal® Transducer Pressure Monitoring System)*, K172458.