December 22, 2022

Edwards Lifesciences LLC
Carmen Chen
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K222216
Trade/Device Name: TruWave Disposable Pressure Transducer
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: November 22, 2022
Received: November 22, 2022

Dear Carmen Chen:

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,

Stephen C. Browning -S

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)*

K222216

Device Name
TruWave Disposable Pressure Transducer

Indications for Use *(Describe)*
The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

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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SECTION 5. 510(K) SUMMARY

510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Contact Person	**Primary Contact** Carmen G Chen Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250 - 5469 Fax: (949) 809 - 2954 Email: Carmen_Chen@edwards.com	**Secondary Contact** Karen O'Leary Sr. Director, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 610-9179 Fax: (949) 809 - 2954 Email: Karen_OLeary@edwards.com
Date Prepared	December 21, 2022	
Trade Name	TruWave™	
Common Name	Disposable Pressure Transducer	
Regulation Number/ Regulation Name	21 CFR 870.2870 / Transducer, Pressure, Catheter Tip	
Product Code	DXO	
Regulation Class	Class II	
Predicate Device	K183413- TruWave Disposable Pressure Transducer (cleared 01 May 2019)	
Device Description	The TruWave Disposable Pressure Transducer is a sterile, single-use device that is used to monitor intravascular, intracranial, and intrauterine pressures. The pressure transducer has a straight, flow-through design across the pressure sensor, and is available with or without the integral flush device. The pressure sensor is a pressure sensitive silicon chip with two electrodes for excitation voltage and two electrodes for signal output. A transparent fluid path with an integral stopcock at one end and an integral flush device (either 3mL or 30mL) at the other end encloses the sensor. The enclosure of the TruWave Disposable Pressure Transducer has a pathway for air to enter the housing and acts as a vent. A disposable cable (available in 10-inch/25 cm and 48-inch/120 cm lengths) attached to the pressure transducer housing interfaces with an Edwards Lifesciences reusable cable that is specifically wired for the monitor being used. The TruWave Disposable Pressure Transducer can be mounted on the patient's	

	arm using an arm strap or it may be mounted on an IV pole in a holder. The TruWave Disposable Pressure Transducer may be a component in various pressure monitoring kits or systems.
Indications for Use/Intended Use	The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.
Comparison to Predicate Device	The subject TruWave Disposable Pressure Transducer device of this Traditional 510(k) is identical to the predicate device cleared in K183413 in terms of indications for use/intended use except for the proposed design, material, and labeling changes to the device. See table below. Differences in technological characteristics do not raise any new concerns of safety and effectiveness. Verification and validation testing for the subject device demonstrate safety and effectiveness. The TruWave Disposable Pressure Transducer has shown to be substantially equivalent to the predicate device for its intended use in a hospital setting or other appropriate clinical environment.
Device Testing	Biocompatibility testing was performed in accordance with ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", issued on September 4, 2020. Electromagnetic compatibility (EMC) and Electromagnetic Immunity (EMI) testing were conducted and comply with the IEC 60601-1, IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC. Electrical safety testing (including defibrillator challenge, dielectric strength, liquid ingress, and leakage current) was performed in accordance with ANSI/AAMI BP22:1994/(R)2016 and IEC 60601-2-34: 2011 Testing (including accuracy, excitation/signal impedance, light sensitivity, symmetry, and overpressure) was conducted per ANSI/AAMI BP22:1994/(R)2016 and IEC 60601-2-34: 2011. Magnetic resonance safety testing was performed based on ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Mechanical testing was performed in accordance with ANSI/AAMI BP22:1994/(R) 2016 and Edwards' design requirements. The usability/human factors of the TruWave Disposable Pressure Transducer were evaluated by healthcare provider users.

Conclusion	All device acceptance criteria were met. Results of non-clinical testing show that the subject device TruWave Disposable Pressure Transducer meets its intended use and demonstrate that the device is as safe, as effective, and performs as well as the predicate device. The differences between the subject device and predicate device do not raise new issues of safety and/or effectiveness. Therefore, the subject device TruWave Disposable Pressure Transducer is substantially equivalent to the predicate device TruWave Disposable Pressure Transducer (K183413).

Function/Parameter	Subject Device (K222216)	Predicate Device (K183413)	Comparison
Device Name	TruWave™ Disposable Pressure Transducer	TruWave™ Disposable Pressure Transducer	Same
510(k) Number	K222216	K183413 (cleared on 01 April 2019)	Not Applicable
Manufacturer	Edwards Lifesciences, LLC	Edwards Lifesciences, LLC	Same
Device Classification	Class II	Class II	Same
Regulation Number	21 CFR §870.2870- Catheter tip pressure transducer	21 CFR §870.2870- Catheter tip pressure transducer	Same
Product Code	DXO	DXO	Same
Intended Use	The Pressure Monitoring Kit with TruWave DPT is used on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.	The Pressure Monitoring Kit with TruWave DPT is used on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.	Same
Indications for Use	The Pressure Monitoring Kit with TruWave DPT is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.	The Pressure Monitoring Kit with TruWave DPT is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.	Same
Operating Principle	The TruWave DPT sensor consists of a silicon chip which when fluid flows through the fluid path allows a piezo-electric diaphragm of the chip to be deflected, which changes resistance of the circuit, which correspondingly causes a change in voltage. This voltage change is transmitted through the cable to a patient monitor.	The TruWave DPT sensor consists of a silicon chip which when fluid flows through the fluid path allows a piezo-electric diaphragm of the chip to be deflected, which changes resistance of the circuit, which correspondingly causes a change in voltage. This voltage change is transmitted through the cable to a patient monitor.	Same
Design	Straight, flow-through design across the pressure sensor	Straight, flow-through design across the pressure sensor	Same
	Housing with curved side grips and arm mount strap slots	Housing with straight side grips and arm mount strap slots	Different because the subject device has curved side grips. No new issues of safety and effectiveness.
	No test port	Has test port	Different because the subject device does not contain a test port. No new issues of safety and effectiveness.

Function/Parameter	Subject Device (K222216)	Predicate Device (K183413)	Comparison
	Has small profile analog pressure sensor with 4 contact pads	Has large profile analog pressure sensor with 5 contact pads	Different because the subject device contains a new, smaller analog pressure sensor. The following tests were conducted: • Biocompatibility • EMC/EMI and Electrical Safety and Performance • MR Safety • Mechanical No new issues of safety and effectiveness.
	Integrated flush device; Molded-in fluid channel as the restrictor to regulate flow	Integrated flush device; Bonded-in PVC capillary tubing component as the restrictor to regulate flow	Different because the subject device does not contain a PVC capillary tubing (i.e., flow restrictor) component. The following tests were conducted: • Biocompatibility • Mechanical No new issues of safety and effectiveness.
	Integrated stopcock; 3-way stopcock body molded into flowpath and stopcock handle mechanically assembled	Integrated stopcock; 3-way stopcock bonded onto housing using UV cure adhesive	Different. The following tests were conducted: • Biocompatibility • Mechanical No new issues of safety and effectiveness.
	Flush pull-tab is angled at 45° from the Housing	Flush pull-tab is angled at 90° from the Housing	Different because the flush pull-tab (i.e., Snap-tab) of the subject device is angled at 45° instead of 90° from the Housing. The following tests were conducted: • Biocompatibility • Mechanical • Design Validation No new issues of safety and effectiveness.

Function/Parameter	Subject Device (K222216)	Predicate Device (K183413)	Comparison
	Disposable cable is 10 inches in length and has four copper wires	Disposable cable is 12 inches in length and has five copper wires	Different because the disposable cable of the subject device is shorter, has one less conductive wire, and has a smaller cross-section than the predicate device. The following tests were conducted: • EMC/EMI and Electrical Safety and Performance • MR Safety • Mechanical No new issues of safety and effectiveness.
Materials	Sensor Gel: Silicone	Sensor Gel: Silicone	Same
	Sensor Gel Cup: Polybutylene terephthalate (PBT)	Sensor Gel Cup: Polycarbonate	Different. The following tests were conducted: • Biocompatibility • EMC/EMI and Electrical Safety and Performance • Mechanical No new issues of safety and effectiveness.
	Resistors: Laser-trimmed integrated circuit	Resistors: Laser-trimmed screened epoxy	Different. The following tests were conducted: • EMC/EMI and Electrical Safety and Performance • MR Safety No new issues of safety and effectiveness.
	Spring terminals: Beryllium copper	Pads and metallization: Palladium silver	Different. The following tests were conducted: • EMC/EMI and Electrical Safety and Performance • MR Safety • Mechanical No new issues of safety and effectiveness.
	Sensor Seal: Silicone gasket	Sensor Seal: Ultraviolet cure (acrylic) adhesive	Different. The following tests were conducted: • Biocompatibility • EMC/EMI and Electrical Safety and Performance • Mechanical No new issues of safety and effectiveness.

Function/Parameter	Subject Device (K222216)	Predicate Device (K183413)	Comparison
	Flush pull-tab: Silicone	Flush pull-tab: Silicone	Different; slight changes in chemical composition. The following tests were conducted: • Biocompatibility • Mechanical No new issues of safety and effectiveness.
	Stopcock body: Polycarbonate	Stopcock body: Polycarbonate	Same
	Housing: Polycarbonate	Housing: Polycarbonate	Same
	Disposable cable jacket: PVC with plasticizer	Disposable cable jacket: PVC with plasticizer	Different. The following test was conducted: • Mechanical No new issues of safety and effectiveness.
	Molded-in Fluid Channel Restrictor: Polycarbonate	Capillary Tubing Restrictor: PVC with DINCH plasticizer	Different; eliminating PVC and integrating the flow restrictor into the flowpath. The following tests were conducted: • Biocompatibility • Mechanical No new issues of safety and effectiveness.
Accessories	Pressure Tubing	Pressure Tubing	Same
	Stopcocks	Stopcocks	Same
	Flush device (3mL/hr or 30 mL/hr)	Flush device (3mL/hr or 30 mL/hr)	Same
	IV Set	IV Set	Same
	VAMP (Venous Arterial Blood Management Protection System)	VAMP (Venous Arterial Blood Management Protection System)	Same
	Disposable holder/TruClip holder	Disposable holder/TruClip holder	Same
	IV Pole Clamp, IV Pole Mount Plate	IV Pole Clamp, IV Pole Mount Plate	Same
	Arm Mount Plate/Strap	Arm Mount Plate/Strap	Same
	Compatible monitor cable	Compatible monitor cable	Same
Sterilization	100% Ethylene Oxide	100% Ethylene Oxide	Same
	E-beam radiation	E-beam radiation	Same