October 23, 2017

Edwards Lifesciences, LLC
Renate MacLaren
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K171996
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: September 21, 2017
Received: September 22, 2017

Dear Renate Maclaren:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171996

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary **K171996**

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Renate A. MacLaren, Ph.D. Senior Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 5783 Fax: (949) 809 – 2941
Date:	June 30, 2017
Trade Name:	TruWave™ Disposable Pressure Transducer
Common Name:	Disposable Pressure Transducer
Classification Name:	Transducer, pressure, catheter tip 21 CFR 870.2870
Product Code:	DXO, Class II
Primary Predicate Device:	K141495, Pressure Monitoring Kit with TruWave Disposable Pressure Transducers (cleared 09/03/2014)
Secondary Predicate Device:	K142749, TruWave Disposable Pressure Transducer (cleared 01/18/2015)
Device Description:	The Edwards Lifesciences Pressure Monitoring Kit with TruWave disposable pressure transducer is a sterile, single-use kit that monitors intravascular blood pressure, intracranial pressure, and intrauterine pressure. The disposable sterile cable (available in 12-inch/30 cm and 48-inch/120 cm lengths) interfaces exclusively with an Edwards Lifesciences cable that is specifically wired for the patient monitor used to display the pressure data. The TruWave Disposable Pressure Transducer has a straight, flow through design, where the fluid is passed across the pressure sensor. The DPT is available either with or without an integral flush device.
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 device of this Traditional 510(k) is identical to its predicate device in terms of intended use/ indications for use, and technology. The proposed changes to the device include a change of sterilization method (100% Ethylene Oxide to E-beam radiation), change in the PVC plasticizer from DEHP to the following non-phthalate plasticizers: Tris-(2-Ethylhexyl) Trimellitate (TOTM) for the drip chamber housing in the IV sets and Cyclohexane-1, 2-dicarboxylic acid diisononyl ester (DINCH®) for tubing. Update to product labeling to reflect changes in sterilization method (from EO to E-beam radiation) and removal of phthalate symbol on all levels of packaging. Clarifying the design verification (electrical) test results in the Instructions for Use 'Performance Specifications' section to comply with AAMI/ ANSI BP22: 1994/(R) 2016. Testing was conducted to ensure that the change in sterilization method and change in materials did not alter the performance of the TruWave DPT kits. The TruWave disposable pressure transducer kits have been shown to be substantially equivalent to the predicate device for its intended use in hospitals and other appropriate clinical environments.
Functional/Safety Testing:	The TruWave disposable pressure transducer kits successfully passed biocompatibility, functional testing, electrical performance and safety testing, and usability testing. The products also passed all biocompatibility testing.
Conclusion:	The subject TruWave Disposable Pressure Transducer kits are substantially equivalent to the predicate TruWave Disposable Pressure Transducer Kits (K141495 and K142749)