May 1, 2019

Edwards Lifeciences, LLC
Ye Seul Kim
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K183413
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: March 29, 2019
Received: April 1, 2019

Dear Ye Seul Kim:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Matthew Hillebrenner
Director (Acting)
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183413

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.

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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

510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	**Primary Contact** Ye Seul Kim Senior Specialist, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 2445 Fax: (949) 809 – 5425 Email: yeseul_kim@edwards.com	**Secondary Contact** Renate MacLaren Senior Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 5783 Fax: (949) 809 – 2941 Email: renate_maclaren@edwards.com
Date Prepared	December 7, 2018	
Trade Name	TruWave™	
Common Name	Disposable Pressure Transducer	
Classification Name	Transducer, pressure, catheter tip (21 CFR 870.2870)	
Regulation Class/Product Code	Class II DXO	
Primary Predicate Device	K171996, TruWave Disposable Pressure Transducer (cleared 10/23/2017)	
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.	
Comparative Analysis	The subject device is identical to the predicate devices in terms of intended use/ indications for use, and technology. The proposed change to the device is a material change to a component of an existing legally	

	marketed device. Testing was conducted to ensure that the change in material did not alter the performance of the TruWave disposable pressure transducer. The subject TruWave disposable pressure transducer has been shown to be substantially equivalent to the predicate devices for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The TruWave disposable pressure transducer kits successfully passed biocompatibility and functional testing.
Conclusion	The subject TruWave disposable pressure transducer kits are substantially equivalent to the predicate TruWave disposable pressure transducer kits (K171996 and K142749).