DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 16, 2015

Edwards Lifesciences, LLC.
Mr. Andrew S. Mazurkiewicz, Jr., MBA/MKT
Senior Associate, Regulatory Affairs
Critical Care
One Edwards Way, CA 92614

Re: K142749
Trade/Device Names: TruWave™ Disposable Pressure Transducers
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DXO
Dated: December 2, 2014
Received: December 4, 2014

Dear Mr. Mazurkiewicz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): **K142749**

Device Name: TruWave™ Disposable Pressure Transducer

Indications For Use:

The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Prescription Use _X__ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5 – 510(k) SUMMARY

TruWave™ Disposable Pressure Transducer 510(k)	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Andrew S. Mazurkiewicz, Jr., MBA/MKT Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250-5167
Date Prepared	September 23, 2014
Trade Name	TruWave™
Common Name	Disposable Pressure Transducer
Classification Name	Transducer, pressure, catheter tip
Regulation Class/Product Code	21 CFR 870.2870 Class II DXO
Predicate Device(s)	K141495 - TruWave Disposable Pressure Transducer (Cleared 9/3/2014)
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.
Device Characteristics	Single Use Sterile (EtO) Prevalent Patient Contact Materials: Polycarbonate, PVC, Soda-Lime Glass
Environment of Use	Healthcare facility/hospital

Materials of Use	Polycarbonate, PVC, Soda-Lime Glass Consensus standards: ISO 10993-4:2002, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2006
Key Performance Specifications	Integral flush device: 3 mL/hr or 30 mL/hr Operating Pressure Range: -50 to + 300 mmHg Nonlinearity and Hysteresis: ±1.5% of reading or ± 1 mmHg, whichever is greater
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	Performance testing was conducted to compare the proposed device to the predicate device. The results of the performance testing indicate that the scientific technology and materials of the proposed device is unchanged from the legally marketed device (predicate). The proposed change to the TruWave disposable pressure transducer has been shown to be safe, effective, and substantially equivalent to the predicate device (TruWave disposable pressure transducer) for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The TruWave disposable pressure transducer has successfully passed functional- performance post MRI exposure, the testing included pressure accuracy (nonlinearity and hysteresis).
Conclusion	The TruWave disposable pressure transducers has been shown to be safe, effective, and substantially equivalent to the predicate device (TruWave disposable pressure transducer) for its intended use in hospitals and other appropriate clinical environments.