



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 19, 2016

Edwards Lifesciences, LLC
Andrew Mazurkiewicz
Sr. Regulatory Affairs Associate
One Edwards Way
Irvine, California 92614

Re: K152980

Trade/Device Name: Flo Trac Sensor, Volume View Sensor
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: December 14, 2015
Received: December 15, 2015

Dear Andrew 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

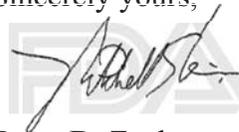
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 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,



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): K152980

Device Name: FloTrac Sensor

Indications For Use:

The FloTrac sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.

Device Name: VolumeView Sensor

Indications For Use:

The VolumeView sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.

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)

Traditional 510(k) – FloTrac and VolumeView Sensor

SECTION 5 – 510(k) SUMMARY

FloTrac and VolumeView Sensor 510(k)	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Andrew S. Mazurkiewicz, Jr., MBA Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250-5167
Date Prepared	October 8, 2015
Trade Name	FloTrac Sensor VolumeView Sensor
Common Name	Dual Disposable Pressure Transducer
Classification Name	Extravascular blood pressure transducer
Regulation Class/Product Code	21 CFR 870.2850 Class II DRS
Predicate Device(s)	k043065 (SE, 4 Nov 2004) - Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor, Models MIHM1 and MIHM1P. k142749 (SE, 16 Jan 2015) TruWave Disposable Pressure Transducer
Device Description	The Edwards Lifesciences FloTrac and VolumeView sensors are sterile, single use devices that monitors pressures when attached to pressure monitoring catheters. The FloTrac and VolumeView sensors are also capable of providing cardiac output measurements when connect to compatible Edwards monitoring systems.
Device Characteristics	Single Use Sterile (EtO) Prevalent Patient Contact Materials: Polycarbonate, PVC, Glass
Environment of Use	Healthcare facility/hospital

Traditional 510(k) – FloTrac and VolumeView Sensor

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 Operating Pressure Range: -50 to + 300 mmHg Nonlinearity and Hysteresis: $\pm 1.5\%$ of reading or ± 1 mmHg, whichever is greater
Indications for Use/Intended Use	The FloTrac and VolumeView sensors are indicated for use for intravascular pressure monitoring. They are also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.
Comparative Analysis	Performance testing was conducted to compare the proposed device(s) to the predicate device(s). The results of performance testing indicate that the scientific technology and materials of the proposed devices are unchanged from the legally marketed device(s) (predicate). The proposed change to the FloTrac and VolumeView Sensors have been shown to be safe, effective, and substantially equivalent to the predicate device(s) (TruWave, FloTrac, and VolumeView sensor) for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The FloTrac and VolumeView Sensors have successfully passed functional performance testing post MRI exposure. This testing included pressure accuracy (nonlinearity and hysteresis).
Conclusion	The FloTrac and VolumeView sensors have been shown to be safe, effective, and substantially equivalent to the respective predicate devices (TruWave, FloTrac, and VolumeView Sensor) for their intended use in hospitals and other appropriate clinical environments.