



March 21, 2025

Edwards Lifesciences, LLC
Aeree Lee
Sr Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K242909

Trade/Device Name: FloTrac sensors; FloTrac Jr sensors; Acumen IQ sensors; VolumeView sensors
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular blood pressure transducer
Regulatory Class: Class II
Product Code: DRS
Dated: February 21, 2025
Received: February 21, 2025

Dear Aeree Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T.
for **Kazmierski -S**

LCDR Stephen Browning

Assistant Director

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

Indications for Use

Submission Number (if known)

K242909

Device Name

FloTrac sensors;
FloTrac Jr sensors;
Acumen IQ sensors;
VolumeView sensors

Indications for Use (Describe)

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. They are intended to be used in adult patients.

The FloTrac Jr 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. The FloTrac Jr sensor is indicated for use in pediatric patients ≥ 12 years of age.

The Acumen IQ 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. They are intended to be used in adult patients.

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.

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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510(K) SUMMARY

FloTrac sensors, Acumen IQ sensors, and VolumeView sensors		
510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA 92614	
Contact Person	<u>Primary Contact</u> Aeree Lee Sr. Manager, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA USA, 92614 Tel.: (949) 250-5155 Email: aeree_lee@edwards.com	<u>Secondary Contact</u> Karen O’Leary Sr. Director, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA USA, 92614 Tel.: (949) 250-0715 Email: karen_oleary@edwards.com
Date Prepared	February 21, 2025	
Trade Name	FloTrac sensor FloTrac Jr sensor Acumen IQ sensor VolumeView sensor	
Regulation Number / Name	21 CFR §870.2850 / Extravascular blood pressure transducer	
Product Code	DRS	
Regulation Class	Class II	
Predicate Devices	FloTrac, Acumen IQ, and VolumeView sensors: K152980 (cleared January 19, 2016) FloTrac Jr sensor: K231248 (cleared September 21, 2023)	
Device Description	The FloTrac, Acumen IQ, and VolumeView sensors are constructed from two disposable pressure transducers that convert a physiological signal (or mechanical pressure) to an electrical signal that is transmitted through the cable to the patient monitor. The sensors have a straight, flow-through design in which fluid is passed directly across the pressure sensor. The sensors are comprised of a pressure sensitive silicon chip with two electrodes for excitation voltage and two electrodes for signal output. A polycarbonate housing with an integral stopcock at one end, and an integral flush device at the other end, encloses the sensors.	
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. They are intended to be used in adult patients. The FloTrac Jr 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. The FloTrac Jr sensor is indicated for use in pediatric patients ≥ 12 years of age.	

FloTrac sensors, Acumen IQ sensors, and VolumeView sensors	
	The Acumen IQ 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. They are intended to be used in adult patients. 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.
Comparative Analysis	The subject devices are identical to the predicate devices in terms of the intended use, indications for use, and technological characteristics, except for the changed pressure tubing and IV set component materials. The differences do not raise any new concerns of safety and effectiveness. The provided risk analysis and performance verification testing demonstrates the subject devices are substantially equivalent to the predicates.
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. Performance verification was performed in accordance with Edwards’ current design requirements. In addition, shelf-life and sterilization validations have been performed to existing specifications. All testing met the existing predetermined acceptance criteria.
Conclusion	Based on the performance testing and the technological characteristics, the FloTrac sensors, Acumen IQ sensors, and VolumeView sensors meet the established performance criteria and are substantially equivalent to the predicate.