August 2, 2024

Edwards Lifesciences, LLC
Kshama Pai
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K233984
Trade/Device Name: Acumen Assisted Fluid Management (AFM) Software Feature
Regulation Number: 21 CFR 870.5600
Regulation Name: Adjunctive Open Loop Fluid Therapy Recommender
Regulatory Class: Class II
Product Code: QMS
Dated: July 3, 2024
Received: July 3, 2024

Dear Kshama Pai:

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.

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,

Aneesh S. Deoras -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233984

Device Name

Acumen Assisted Fluid Management (AFM) Software Feature

Indications for Use *(Describe)*

The Edwards Lifesciences Acumen Assisted Fluid Management (AFM) Software Feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM Software Feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM Software Feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

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.

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510(k) #: K233984

510(k) Summary

Prepared on: 2024-07-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Edwards Lifesciences, LLC
Applicant Address	One Edwards Way Irvine CA 92614 United States
Applicant Contact Telephone	9492504457
Applicant Contact	Ms. Kshama Pai
Applicant Contact Email	kshama_pai@edwards.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Acumen Assisted Fluid Management (AFM) Software Feature
Common Name	Adjunctive open loop fluid therapy recommender
Classification Name	Adjunctive Open Loop Fluid Therapy Recommender
Regulation Number	870.5600
Product Code	QMS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223865	Acumen Assisted Fluid Management (AFM) Software Feature on Hemo Sphere Advanced Monitoring Platform	QMS

Device Description Summary

21 CFR 807.92(a)(4)

The Acumen AFM Software Feature (core AFM algorithm + AFM Graphical User Interface) was originally granted in De Novo, DEN190029, on November 13, 2020, to inform clinicians about a patient's fluid responsiveness. The performance of the AFM Software Feature in predicting a patient's fluid responsiveness is measured using response rate and is calculated by reporting the percentage of followed AFM recommendations ("Fluid Bolus Suggested" and "Test Bolus Suggested" prompts) that have the desired change in stroke volume (SV), divided by the total number of AFM recommendations.

With this submission, Edwards is seeking clearance for the addition of the AFM Prompt Reclassifier algorithm (AFM PR algorithm) to the Acumen AFM Software Feature. The AFM Prompt Reclassifier algorithm is intended to be used in conjunction with the core AFM algorithm to re-assess the fluid bolus recommendations provided by the core AFM algorithm. It analyzes the patient's current hemodynamics for either confirming (corroborating) the original prompt or reclassifying the prompts (i.e., reclassify a "Test Bolus Suggested" prompt to a "Fluid Bolus Suggested" prompt or vice versa). In doing so, it acts as a secondary check for the fluid bolus prompts such that a greater number of the "Fluid Bolus Suggested" prompts lead to the desired change in stroke volume. Through refined prompt adjustments informed by real-time hemodynamic data, the AFM PR algorithm aims to improve patient responsiveness, thereby optimizing the impact of the AFM Software Feature on patient hemodynamics.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Edwards Lifesciences Acumen Assisted Fluid Management (AFM) Software Feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM Software Feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM Software Feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject and predicate device (most recently cleared in K223865 on June 09, 2023) have the same intended use and indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate device have the following similarities:

• The subject and predicate devices utilize the same predictive core AFM algorithm and the same AFM GUI (i.e., same fundamental technology) to obtain AFM output fluid bolus prompts.
• The functionality and use of the AFM Software Feature remains unchanged. No new output prompts or suggestions are generated and hence, the modifications made to the AFM Software Feature do not constitute a new intended use.
• The timing, volume, and number of fluid bolus prompts of the AFM Software Feature remain equivalent between the subject and predicate device.
• The sensitivity, specificity, positive predictive value and negative predictive value remain the same between the subject device and predicate device.

The following key difference exists between the subject and predicate devices:

• The subject device utilizes an additional algorithm with the cleared core AFM algorithm, which leads to an improved response rate of the "Fluid Bolus Suggested" prompts (i.e., greater number of these prompts lead to desired changes in patient's stroke volume).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Software verification and validation activities were performed in accordance with ANSI/AAMI/IEC 62304, Medical Device Software – Software Life Cycle Processes, FDA's Guidance on Content of Premarket Submissions for Software Contained in Medical Devices (issued June 14, 2023), General Principles of Software Validation (issued January 11, 2002), and Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016), as well as the special controls specified in De Novo Grant, DEN190029.

Algorithm performance was analyzed on the archived dataset from the US IDE Study, G170204. This dataset consisted of 1229 data points from 307 patients from 9 independent U.S. sites. The primary objective of the validation was to demonstrate the impact on the response rate of the AFM Software Feature's fluid bolus prompts due to the addition of AFM Prompt Reclassifier algorithm. The resulting rates for the AFM PR algorithm and predicate/cleared core AFM algorithm were compared and demonstrated an improvement in response rate for "Fluid Bolus Suggested" prompts, thus demonstrating that the AFM PR algorithm met the predefined acceptance criteria. The results demonstrate that the differences in the response rates for the fluid bolus suggestions introduced by the AFM PR algorithm do not raise any concerns of safety and effectiveness for the cleared AFM Software feature. These non-clinical design control activities form the basis for the substantial equivalence between the subject and the predicate/ existing AFM Software feature.

The results of these performance testing activities demonstrate that the specified design requirements were met, and that the modifications in scope of this submission do not adversely affect the safety and effectiveness of the AFM Software Feature. Based on the information presented within this 510(k) and the testing performed, the AFM Software Feature with subject modifications for introduction of AFM PR algorithm is substantially equivalent to the predicate AFM Software Feature (last cleared in K223865 on June 09, 2023).