



November 13, 2020

Edwards Lifesciences
Lisa Gilman
Distinguished Regulatory Affairs Program Manager One Edwards Way
Irvine, California 92614

Re: DEN190029

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: June 3, 2019

Received: June 4, 2019

Dear Lisa Gilman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Acumen Assisted Fluid Management (AFM) Software Feature, a prescription device under 21 CFR Part 801.109 with the following indications for use:

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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Acumen Assisted Fluid Management (AFM) Software Feature, and substantially equivalent devices of this generic type, into Class II under the generic name adjunctive open loop fluid therapy recommender.

FDA identifies this generic type of device as:

Adjunctive open loop fluid therapy recommender. The adjunctive open loop fluid therapy recommender is a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict a patient's estimated response to fluid therapy. The device is intended for

adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 3, 2019, FDA received your De Novo requesting classification of the Acumen Assisted Fluid Management (AFM) Software Feature. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Acumen Assisted Fluid Management (AFM) Software Feature into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Acumen Assisted Fluid Management (AFM) Software Feature can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Delay in monitoring or treatment.	Software verification, validation, and hazard analysis; Usability assessment; and Labeling
Inappropriate or missed treatment due to over-reliance on software recommendation which is affected by: algorithm or software error, or inaccurate input from sensors or users	Software verification, validation, and hazard analysis; Non-clinical performance testing; Usability assessment; Clinical performance testing; and Labeling
Fluid overload due to over-reliance on software recommendations which are affected by: algorithm or software error, or inaccurate input from sensors or users	Software verification, validation, and hazard analysis; Non-clinical performance testing; Usability assessment; Clinical performance testing; and Labeling

In combination with the general controls of the FD&C Act, the adjunctive open loop fluid therapy recommender is subject to the following special controls:

1. Clinical performance testing under anticipated conditions of use must fulfill the following:

- a. A summary of the clinical performance testing must include the relevant patient demographics, and any statistical techniques used for analyzing the data;
 - b. Subjects must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified;
 - c. Testing must demonstrate the recommendation consistency using the expected range of data sources and data quality encountered in the intended patients, users, and environments; and
 - d. Testing must evaluate the relationship between algorithm recommendations, therapeutic actions, and predicted physiological event or status.
2. A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must be provided, including:
- a. A full characterization of the software technical parameters, including algorithms;
 - b. A description of the expected recommendation, accounting for differences in patient condition and environment;
 - c. A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) that affect the device's recommendations;
 - d. A characterization of algorithm sensitivity to variations in user inputs;
 - e. A characterization of sensor accuracy and performance;
 - f. A description of sensor data quality control measures; and
 - g. Safeguards to reduce the possibility of fluid overload.
3. A scientific justification for the validity of the algorithm(s) must be provided. This justification must include non-clinical verification and validation of the algorithm calculations and clinical validation using an independent data set.
4. A human factors and usability engineering assessment must be provided.
5. Labeling must include:
- a. A description of what the device measures, how the device decides to issue recommendations, and the expected range of frequency of recommendations, while accounting for differences in patient condition and environment;
 - b. Detailed information regarding limitations of the device's algorithm, and key assumptions made when the device issues a recommendation;
 - c. Warnings identifying sensor acquisition factors that may impact measurement results;
 - d. Warnings identifying user errors that affect the device's recommendations;
 - e. Detailed information regarding the expected impact of user input errors on the device recommendations;
 - f. Guidance for interpretation of the device's recommendations, including a description that the recommendation is adjunctive to other physical vital sign parameters and patient information;
 - g. Description of the impact of the compatible sensor(s) on the device's performance;
 - h. The expected performance of the device for all intended patients, users, and environments;
 - i. Relevant characteristics of the patients studied in the clinical validation (such as age, gender, race or ethnicity, and patient condition) and a summary of validation results; and
 - j. Description of the software safeguards that are in place to prevent fluid overload, and description of any limitation of the software safeguards.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the adjunctive open loop fluid therapy recommender they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Biniyam Taddese at 240-402-6570.

Sincerely,

for

Bram Zuckerman, M.D.

Director

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health