June 8, 2023

Edwards Lifesciences LLC
Varad Raghuwanshi
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K230057
Trade/Device Name: Acumen Hypotension Prediction Index (HPI)
Regulation Number: 21 CFR 870.2210
Regulation Name: Adjunctive Predictive Cardiovascular Indicator
Regulatory Class: Class II
Product Code: QAQ
Dated: January 6, 2023
Received: January 9, 2023

Dear Varad Raghuwanshi:

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. 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 located 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.

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) 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 Act); 21 CFR 1000-1050.

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 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. Kazmierski -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230057

Device Name
Acumen Hypotension Prediction Index

Indications for Use *(Describe)*
Acumen Hypotension Prediction Index:

The Edwards Acumen Hypotension Prediction Index software feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and is not intended to make therapeutic decisions solely on the Acumen Hypotension Prediction Index (HPI) parameter.

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) Summary – Acumen Hypotension Prediction Index (HPI)

I. Submitter:

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Varad Raghuwanshi Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 Telephone: (949) 756-4502 Fax: (949) 809-2972
Date Prepared:	June 8, 2023

II. Device Information:

Device Name	Acumen Hypotension Prediction Index (HPI)	
Trade Name:	Acumen Hypotension Prediction Index (HPI) feature for Minimally Invasive and Non-Invasive technology	
Common Name:	Adjunctive Predictive Cardiovascular Indicator	
Classification Name:	Adjunctive Predictive Cardiovascular Indicator	21 CFR 870.2210
Product Code and Regulatory Class:	QAQ, Class II	

III. Predicate Device

Primary Predicate Device:	HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K203687 cleared May 28th, 2021, utilized for the Acumen Hypotension Prediction Index software feature.
Additional Predicate Devices:	Acumen Hypotension Prediction Index feature by Edwards Lifesciences DEN160044, granted March 16, 2018, utilized for the Acumen Hypotension Prediction Index software feature.

IV. Device Description

Device Description:

The Acumen Hypotension Prediction Index parameter (HPI) provides the clinician with the likelihood that the patient may be trending toward a hypotensive event. The Acumen HPI feature is intended for use in surgical or non-surgical patients.

By default, the software defines a hypotensive event as mean arterial pressure (MAP) < 65 mmHg for at least one minute in duration. This MAP target is adjustable and can be changed to 55, 60, 70, 75, 80 or 85 mmHg.

V. Indications for Use:

Note: *The Indication for Use statement for Acumen Hypotension Prediction is similar to what was previously cleared in K203687 May 28th, 2021, with the exception of removal of the statement to define hypotensive event as the users will now have the option to use the default 65 target or alternatively select a MAP target of 55, 60, 70, 75, 80 or 85 mmHg for hypotension. In addition, the indication for Acumen HPI when used with the non-invasive (ClearSight) technology has been expanded to include non-surgical patients.*

Acumen Hypotension Predication Index (HPI)

The Edwards Acumen Hypotension Prediction Index software feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring.

The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference

only and is not intended to make therapeutic decisions solely on the Acumen Hypotension Prediction Index (HPI) parameter.

Intended Use: The Acumen Hypotension Prediction Index (HPI) software feature used on a compatible monitoring platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

Parameter	Description	Patient Population	Hospital Environment
HPI	Acumen Hypotension Prediction Index	Adult only	Surgical and non-surgical

VI. Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices are based on the following same technological elements:

- Predictive Algorithm: The subject and predicate (initially cleared in DEN160044 and later cleared in K203687 on May 28th, 2021, for Edwards noninvasive technology have the same core predictive algorithm for Acumen Hypotension Predication Index (HPI).

The following technological difference exist between the subject and predicate devices:

- Acumen HPI algorithm enhancement: An enhancement has been made to the existing HPI software feature cleared in K203687 (May 28th, 2021) to include an option to allow the clinician to adjust the Mean Arterial Pressure (MAP) target for hypotension (55, 60, 70, 75, 80, 85 mmHg) in addition to the existing default MAP target of 65 mmHg without making any changes to the core HPI algorithm and the original HPI algorithm parameters.

The purpose of this 510(k) submission is to obtain clearance for the following modifications to the Acumen Hypotension Prediction Index (K203687 (May 28th, 2021):

- **Modification to the Acumen Hypotension Prediction Index (HPI) software feature to introduce adjustable MAP targets for hypotension (previously cleared in K203687 on May 28th, 2021):**

  - Algorithm Modification: Update to the existing Acumen™ HPI Algorithm

    The existing Acumen Hypotension Prediction Index software feature for Edwards minimally invasive and noninvasive technology has been modified to include an option to allow the clinician to adjust the Mean Arterial Pressure (MAP) target for hypotension (55, 60, 70, 75, 80, 85 mmHg) in addition to the existing default MAP target of 65 mmHg.

- **Modifications to the labelling related to the Acumen Hypotension Prediction Index software feature cleared in K203687, cleared May 28th, 2021):**

  - Updated Indication for Use statement and the Clinical validation information to align with the proposed adjustable MAP targets for hypotension:

    The current Acumen Hypotension Prediction Index software feature for minimally invasive and noninvasive technology, cleared in K203687 on May 28th, 2021, defines a hypotensive event as mean arterial pressure < 65 mmHg for at least one minute in duration. Due to the proposed change to introduce adjustable MAP targets for hypotension, users will now have the option to use the default 65 target or alternatively select a MAP target of 55, 60, 70, 75, 80 or 85 mmHg. Hence the current definition of a hypotensive event "(*defined as mean arterial pressure < 65 mmHg for at least one minute in duration)"* is no longer applicable and has been removed from the indication for use statement.

    In addition, the clinical validation section for Acumen HPI has been updated to represent the clinical validation results for the proposed adjustable MAP targets for hypotension.

  - Indication expansion to include nonsurgical patients for Acumen HPI for noninvasive technology:

The current indication for Acumen Hypotension Prediction Index when used with Edwards ClearSight (Noninvasive) technology has been expanded to include nonsurgical patients.

Performance Data:

The following verification activities were performed in support of a substantial equivalence determination for the modifications being made as part of this submission.

Algorithm Verification:

Algorithm performance was tested using clinical data. The results establish that the usage of the HPI algorithm with the adjustable Mean Arterial Pressure (MAP) targets for hypotension (55, 60, 70, 75, 80, 85 mmHg) did not adversely affect the safety and effectiveness of the subject device.

In addition, algorithm verification is completed using non-surgical clinical data collected retrospectively to support expanded non-surgical indication for Acumen Hypotension Prediction Index when used with Edwards ClearSight (Noninvasive) technology.

Usability Study

Usability study was conducted per FDA's guidance document "*Applying Human Factors and Usability Engineering to Medical Devices*" to validate the updated instructions and to assess the success of the proposed modification to reduce the risks to acceptable levels without introducing any new unacceptable risks.

The usability study demonstrated that the intended users can perform primary operating functions and critical tasks of the system without any usability issues that may lead to patient or user harm.

Conclusions

The technological characteristics of the subject and predicate devices are identical. The modified Acumen Hypotension Prediction Index feature with adjustable MAP targets for hypotension algorithm has successfully passed the functional and performance testing including software verification and validation and bench studies. The testing performed demonstrates that the Acumen Hypotension Prediction Index with the subject modification and expanded indication is substantially equivalent to the legally marketed predicates.