Edwards Lifeciences, LLC
Lisa Gilman
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K183646
Trade/Device Name: Acumen Hypotension Prediction Index
Regulation Number: 21 CFR 870.2210
Regulation Name: Adjunctive Predictive Cardiovascular Indicator
Regulatory Class: Class II
Product Code: QAQ
Dated: May 16, 2019
Received: May 17, 2019

Dear Lisa Gilman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Hillebrenner
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183646

Device Name
Acumen Hypotension Prediction Index

Indications for Use *(Describe)*
The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) 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 no therapeutic decisions should be made based solely on the 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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SECTION 5 – 510(k) SUMMARY

Acumen™ Hypotension Prediction Index	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Lisa Gilman
Date Prepared	May 17, 2019
Trade Name	Acumen™ Hypotension Prediction Index
Common Name	Adjunctive Predictive Cardiovascular Indicator
Classification Name	Adjunctive Predictive Cardiovascular Indicator
Regulation Class / Product Code	21 CFR 870.2210/Class II/QAQ
Predicate Device(s)	Acumen Hypotension Prediction Index, DEN160044
Device Description	The Acumen Hypotension Prediction Index Feature (DEN160044) consists of software running on the Edwards Lifesciences EV1000 Clinical Platform (DEN160044) and HemoSphere Advanced Monitoring Platform (K180881) paired with the FloTrac IQ or Acumen IQ extravascular blood pressure transducer (K152980) and a radial arterial catheter. The software includes the Acumen Hypotension Prediction Index (HPI), the Dynamic Arterial Elastance Parameter (Ea_{dyn}), the Systolic Slope Parameter (dP/dt), and additional graphical user interface features. The Acumen Hypotension Prediction Index is an index related to the likelihood of a patient experiencing a hypotensive event (defined as mean arterial pressure (MAP) < 65 mmHg for one minute in duration) within 15 minutes, where zero (0) indicates low likelihood and one hundred (100) indicates high likelihood. The Acumen Hypotension Prediction Index, HPI, should not be used exclusively to treat patients. A review of the patient's hemodynamics is recommended prior to initiating treatment.

Indications for Use/Intended Use	The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) 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 no therapeutic decisions should be made based solely on the Hypotension Prediction Index (HPI) parameter.

Comparison to Predicate Device	The Acumen™ Hypotension Prediction Index Feature Software (DEN160044, granted March 16, 2018)
	
	Modifications
	• The labeling of the EV1000A Clinical Platform and the HemoSphere Advanced Monitoring Platform has been modified to expand the indications for use from surgical [operating room (OR)] patients to surgical or non-surgical patients.
	
	• The graphical user interface of the EV1000A Clinical Platform and the HemoSphere Advanced Monitoring Platform has been modified to define:
	  • dP/dt parameter as systolic slope; and,
	  • Ea_{dyn} parameter as dynamic arterial elastance.
	
	• There are no modifications to the hardware of the monitoring platforms.

Performance Data	**Clinical Performance** Clinical performance data were provided to demonstrate substantial equivalence of use of the Acumen™ Hypotension Prediction Index software.
Conclusion	**Overall Conclusion** The clinical performance data demonstrate that the Acumen™ Hypotension Prediction Index software used in non-surgical patients is substantially equivalent to use in surgical patients.