July 26, 2023

Edwards Lifesciences, LLC
Michelle Ducca
Manager, Regulatory Affairs
1 Edwards Way
Irvine, California 92614

Re: K231038
Trade/Device Name: Global Hypoperfusion Index (GHI) Algorithm
Regulation Number: 21 CFR 870.2210
Regulation Name: Adjunctive predictive cardiovascular indicator
Regulatory Class: Class II
Product Code: QNL
Dated: June 14, 2023
Received: June 15, 2023

Dear Michelle Ducca:

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,

for Robert T. Kazmierski -S

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)*
K231038

Device Name
Global Hypoperfusion Index (GHI)

Indications for Use *(Describe)*
The Global Hypoperfusion Index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm provides the risk of a global hypoperfusion event (defined as SvO2 ≤ 60% for at least 1 minute) occurring in the next 10-15 minutes.

The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter.

The GHI algorithm is considered to provide additional information regarding the patient's predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions.

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 – HemoSphere Advanced Monitoring Platform

Sponsor: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

Establishment Registration Number: 2015691

Contact Person: Michelle Ducca
Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
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Telephone: (949) 250-4113

Date: April 10, 2023

Device/Trade Name: Global Hypoperfusion Index Feature *(subject)*

Common Name: Medium-term adjunctive predictive cardiovascular indicator

Classification Name: Medium-term adjunctive predictive cardiovascular indicator — 21 CFR 870.2210

Product Code and Regulatory Class: QNL, Class II

Primary Predicate: HemoSphere Advanced Monitoring Platform, manufactured by Edwards Lifesciences, K203687 cleared May 28, 2021, is being utilized for substantial equivalence to the Acumen Hypotension Prediction Index (HPI) software feature which has the same intended use and similar indications for use and the same principle of operation as the HPI feature. The subject device has similar technological characteristics and has been demonstrated to be safe and effective and does not raise different questions of safety and effectiveness from the primary predicate.

Additional Predicates: CLEWICU System (*K200717, cleared January 9, 2021)* manufactured by CLEW Medical Ltd., is being utilized for substantial equivalence to the Global Hypoperfusion Index (GHI) feature, which includes similar principles of

operation and indications for use related to the patient's predicted future risk for clinical deterioration.

Device Description: The Global Hypoperfusion Index (GHI) parameter provides the clinician with physiological insight into a patient's likelihood of a global hypoperfusion event on average 10-15 minutes before mixed venous oxygen saturation (SvO2) reaches 60%. The GHI feature is intended for use in surgical or non-surgical patients. The product predictions are adjunctive for reference only and no therapeutic decisions should be made based solely on the GHI parameter.

Indications for Use:

Global Hypoperfusion Index (GHI) Software Feature

The Global Hypoperfusion Index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm provides the risk of a global hypoperfusion event (defined as SvO2 ≤ 60% for at least 1 minute) occurring in the next 10-15 minutes.

The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter.

The GHI algorithm is considered to provide additional information regarding the patient's predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions.

Intended Use: The Global Hypoperfusion Index (GHI) 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
GHI	Global Hypoperfusion Index	Adult only	Surgical and non-surgical

Comparison to Predicate Device: The HemoSphere Advanced Monitoring Platform, manufactured by Edwards Lifesciences, with Acumen Hypotension Prediction Index, K203687 cleared May 28, 2021 for Edwards technology and CLEWICU System, K200717 cleared January 9, 2021 are chosen as predicates since both are predictive algorithms for hemodynamic instability/ deterioration with the same indications for use/intended use, principle of operation and similar technological characteristics as the subject GHI algorithm.

The Global Hypoperfusion Index (GHI) algorithm provides an index from 0 to 100 where the higher the value, the increased likelihood that a global

hypoperfusion event will occur. The GHI algorithm alerts the clinician on average 10-15 minutes before mixed venous oxygen saturation (SvO2) reaches 60%. The subject device has the same intended use as the primary predicate (HPI) to be used by qualified personnel or trained clinicians in the critical care setting. The subject and primary predicate (HPI) and additional predicate (CLEWICU) are all intended for use in adult patients and provide physiological insight into future likelihood of hemodynamic instability. Both the subject GHI and additional predicate (CLEWICU) provide the user with a predicted future risk for clinical deterioration.

Performance testing executed shows that there are no new concerns of safety and effectiveness.

The purpose of this Traditional 510(k) is to obtain clearance for the Global Hypoperfusion Index (GHI) algorithm.

Comparison of Technological Characteristics with Predicates:

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

- Predictive algorithm using a machine-learning model
- Calculation of the risk and likelihood of a future clinically significant hemodynamic cardiovascular event
- Device inputs use real-time patient health data for analysis to generate prediction
- Alert the physician when the patient's risk has reached a predefined threshold. Both devices provide predictions in a timeframe that permits appropriate clinical review and action

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. Algorithm verification was performed per FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005) and ANSI/AAMI/IEC 62304:2006/A1:2016, *Medical Device Software – Software Life Cycle Processes* and FDA Guidance *General Principles of Software Validation* (issued January 11, 2022). The algorithm was tested at the algorithm level to ensure the safety of the device. All tests passed.

No clinical trial was performed in support of the subject 510(k). However, patient waveforms were collected in support of the development and validation of the GHI algorithm.

Clinical Performance

Prospective analyses of retrospective clinical data from multiple independent datasets, comprised of data from a diverse set of patients over the age of 18 years undergoing surgical procedures with invasive monitoring, were analyzed to verify the safety and performance of the subject device.

Conclusions

Overall Conclusion:

The subject Global Hypoperfusion Index (GHI) algorithm has successfully passed functional and performance testing, including software and algorithm verification and validation and bench studies. Completion of all performance verification and validation activities demonstrated that the subject device meets the predetermined design and performance specifications. Verification activities performed confirmed that the differences in the features did not adversely affect the safety and effectiveness of the subject device. The testing performed demonstrates that the Global Hypoperfusion Index (GHI) is substantially equivalent to its legally marketed predicates.