November 17, 2023

Edwards Lifesciences, LLC
Kshama Pai – Sr. Regulatory Affairs Specialist
One Edwards Way
Irvine, California 92614

Re: K230612
Trade/Device Name: Edwards Algorithm for Measurement of Blood Hemoglobin
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: October 19, 2023
Received: October 19, 2023

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,

Stephen C. Browning -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)*
K230612

Device Name
The Edwards Algorithm for Measurement of Blood Hemoglobin

Indications for Use *(Describe)*
The Edwards Algorithm for Measurement of Blood Hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥ 40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight Oximeter Cable and non-invasive ForeSight sensors (large) in cerebral locations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – Edwards Algorithm for Measurement of Blood Hemoglobin

Sponsor: Edwards Lifesciences, LLC
One Edwards Way
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Establishment Registration Number: 2015691

Contact Person: Kshama Pai
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Date: November 17, 2023

Trade Name: Edwards Algorithm for Measurement of Blood Hemoglobin

Common Name: Tissue Oximetry

Classification Name: Oximeter, Tissue Saturation (Non-Invasive) 21 CFR 870.2700

Product Code: MUD, Class II

Primary Predicate: HemoSphere ForeSight Oximeter Cable (FSOC) on the HemoSphere Advanced Monitoring Platform, manufactured by Edwards Lifesciences, most recently cleared under K223127 on November 07, 2022, is being utilized as the Primary Predicate to establish substantial equivalence to the intended use, technology, and principle of operation.

Reference Devices:

- RAPIDPoint 500, manufactured by Siemens Healthcare Diagnostics and cleared via K113216 on May 03, 2012, has been chosen as a reference device as it has the same intended use and the same technological feature as the subject algorithm for measurement of the total hemoglobin values in blood.

- Masimo Rad-97 Pulse CO-Oximeter, manufactured by Masimo Corporation and cleared via K193626 on August 10, 2020, has been chosen as a reference device as it is a cleared device analogous in function to the subject device. Additionally, it was validated using the same strategy as the subject device, by comparing performance against a laboratory co-oximeter.

Device Description:

The Edwards Algorithm for Measurement of Blood Hemoglobin is intended for continuously and non-invasively monitoring the relative and total hemoglobin values in the blood of patients requiring advanced hemodynamic monitoring in a critical care environment. The outputs of the algorithm include the relative changes in total hemoglobin in blood (ΔtHb) and total hemoglobin in blood (tHb) parameters and are derived from the relative change in concentration of total tissue hemoglobin (ΔctHb parameter) measured by the ForeSight Oximeter Cable on the HemoSphere Advanced Monitoring Platform (K213682, cleared June 22, 2022).

The subject algorithm provides relative blood hemoglobin (ΔtHb; measured in g/dL of blood) values continuously as a change over time from 0 g/dL. It can also be calibrated using an optional input of reference blood hemoglobin measurements such as ones obtained *in vitro* from a blood gas analyzer. When calibrated, it provides the value of total blood hemoglobin (tHb).

Additionally, the algorithm also provides three secondary output flags:

- **DoNotCalibrate Flag:** This flag is intended to indicate when a calibration should not be performed.
- **Recalibrate Flag:** This flag is intended to indicate when a new calibration is recommended.
- **Unstable Flag:** This flag is intended to indicate when the input signal (ΔctHb) is unstable.

Indications for Use:

The Edwards Algorithm for Measurement of Blood Hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥ 40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight Oximeter Cable and non-invasive Foresight Sensors (large) in cerebral locations.

Intended Use:

The Edwards Algorithm for Measurement of Blood Hemoglobin is intended for use as an adjunct monitor of relative and total hemoglobin concentration of blood in individuals at risk for reduced-flow or no-flow ischemic states in surgical and ICU settings.

Comparison to Predicate Device:

The HemoSphere ForeSight Oximeter Cable, manufactured by Edwards Lifesciences, and cleared via K223127 on November 07, 2022, is being utilized as the Primary Predicate for establishing substantial equivalence to the intended functionality principle of operation, and technological characteristics as the proposed algorithm.

The HemoSphere ForeSight Oximeter Cable of the HemoSphere Advanced Monitoring Platform, when used in conjunction with the HemoSphere

Monitor and ForeSight sensors, is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation and relative changes in total hemoglobin of blood in tissue under the sensors in individuals at risk for reduced flow or no-flow ischemic states.

The subject Edwards Algorithm for Measurement of Blood Hemoglobin is also intended for continuous, non-invasive monitoring of hemoglobin. Additionally, it derives its outputs from the existing ΔctHb parameter (relative change in concentration of total hemoglobin in tissue under sensor) measured by the ForeSight Oximeter Cable using large ForeSight sensor sizes in cerebral locations. As such, it utilizes the same technology (i.e., existing StO_2 algorithm) and principles of operation (continuous, non-invasive tissue oximetry measurement) as the predicate,. Therefore, the ForeSight Oximeter Cable has been chosen as the *Primary Predicate*.

The subject device utilizes a *Reference Device*, RAPIDPoint 500; (cleared via K113216 on May 03, 2012) to establish substantial equivalence for these new parameters. This predicate device is intended for the determination of total hemoglobin concentration of blood (measured in g/dL). As such, it has the same intended use and the same technological feature for measurement of the total hemoglobin values in blood as the subject algorithm.

Masimo Rad-97 Pulse CO-Oximeter, manufactured by Masimo Corporation and cleared via K193626 on August 10, 2020, has been chosen as a *Reference Device* as it is a cleared device analogous in function to the subject device. Additionally, it was validated using the same strategy as the subject device; by comparing performance against a laboratory co-oximeter.

The subject device and the predicate devices have the following key similarities:

- Subject and primary predicate devices have the same intended use and similar indications for use as an adjunct monitor for continuous, non-invasive hemoglobin measurement
- Subject and primary predicate devices have the same principle of operation (tissue oximetry using near-infrared spectroscopy (NIRS) signals of 690, 735, 770, 810 and 870 nm measured through independent front-end signal acquisition channels)
- Subject and primary predicate devices utilize ForeSight Sensors and Foresight Oximetry Cable with existing StO_2 algorithm to measure relative change in total hemoglobin of blood in tissue under sensors (ΔctHb)

The subject device and the predicates have the following key differences:

- Subject device is only intended to be used in adult population, whereas the primary predicate device is intended for adults and pediatric population.

- Subject device measures relative changes and absolute values of total blood hemoglobin measured in g/dL of blood, whereas primary predicate only measures relative changes in tissue hemoglobin in blood under sensor measured in μmoles/L tissue under sensor.
- Subject and reference device, RAPIDPoint 500, include proposed indication and associated performance specification for measurement of total blood hemoglobin, whereas the primary predicate device did not have an indication and specification for this particular parameter.

The new parameter is intended to be adjunct to clinical measurement of blood hemoglobin and is not intended to replace clinical decision making. No therapeutic decisions are intended to be taken solely on its account. Performance testing included head-to head comparison against the reference device and utilizes validation methodology applied by reference predicate device. The successful results show device performs as intended and do not raise any concerns of safety and effectiveness.

Performance Data (Bench and/or Clinical):

The following verification activities were performed for ensuring the safety and effectiveness of the proposed algorithm and to support substantial equivalence to its primary predicate, HemoSphere ForeSight Oximeter Cable, and reference device, RAPIDPoint 500.

Software Verification

Software verification was performed per ANSI/AAMI/IEC 62304, *Medical Device Software - Software Life Cycle Processes*, and FDA's Guidance Documents for Industry and FDA Staff on *Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005) and *General Principles of Software Validation* (issued January 11, 2002). The Edwards Algorithm for Measurement of Blood Hemoglobin was tested at the algorithm level to ensure the safety of the device.

Retrospective analyses were performed on data collected from randomly selected 83 patients across 5 US and EU sites, independent of the device development. The breakdown of subjects per site and demographic information is provided below.

Dataset Site	Location	Combined
1	Amsterdam, The Netherlands	27 (32.53%)
2	Santander, Spain	8 (9.64 %)
3	Greenville, North Carolina, USA	18 (21.69%)
4	Sacramento, California, USA	11 (13.25%)
5	Chicago, Illinois, USA	19 (22.89%)
	% US Representation	57.8%
	Total	n = 83

n=83	Demographic Summary Statistics
Race and Ethnicity	32 (38.55%) White, 11 (13.25%) Black, 2 Asian (2.41%), 2 Hispanic (2.41%), 1 (1.21%) Hindustani, 35 (42.17%) unknown/not reported
Sex	58 (69.88%) Male, 25 (30.12%) Female
Weight/BMI	83.7 kgs (46.0 – 128.0 kgs)

The subject device was validated for its accuracy in measuring relative and absolute values of total blood hemoglobin when compared to laboratory co-oximeter. Performance data were assessed using Root Mean Squared Error (RMSE or ARMS) and Bland-Altman analyses. 95% confidence intervals for RMSE were generated based on cluster bootstrapping with resampling of the subjects. 95% confidence intervals for Bland-Altman analyses were calculated using methods that account for between subjects and within subject variation. The results demonstrated that the subject device subject device met the acceptance criteria of 1g/dL with a bias close to 0 and precision less than 1g/dL and performed equally well across the intended use population for different demographic factors (race, ethnicity, age, gender, weight) and sites, thereby, showing substantial equivalence to the predicate.

Clinical Performance

No clinical trial was performed in support of the subject 510(k) submission.

Conclusions

Overall Conclusion:

The subject, Edwards Algorithm for Measurement of Blood Hemoglobin, has successfully passed functional and performance testing, including software verification and bench studies. Completion of all performance verification activities demonstrated that the subject device meets its predetermined design and performance specifications. The conducted testing demonstrates that the new software algorithm is substantially equivalent to its legally marketed predicate devices, and the differences in the features and design do not adversely affect the safety and effectiveness of the subject device.