February 10, 2021

Edwards Lifesciences, LLC
Michelle Ducca
Sr. Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K203490
Trade/Device Name: FORE-SIGHT ELITE Absolute Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: November 25, 2020
Received: November 27, 2020

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,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203490

Device Name
FORE-SIGHT ELITE Absolute Tissue Oximeter

Indications for Use *(Describe)*
The non-invasive Fore-Sight Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

- When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 Kg.

- When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥ 3 Kg.

- When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects < 8 Kg and non-cerebral use on pediatric subjects < 5 Kg.

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 – FORE-SIGHT ELITE Absolute Tissue Oximeter

I. Submitter:

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

Establishment Registration Number: 2015691

Contact Person: Michelle Ducca
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Date Prepared: November 25, 2020

II. Device Information

Platform Name (Name of the Device): Fore-Sight Elite Absolute Tissue Oximeter

Trade Name: Fore-Sight Elite Absolute Tissue Oximeter

Common Name: Fore-Sight Elite Monitor

Classification Name: Oximeter
21 CFR 870.2700

Product Code and Regulatory Class: MUD, Class II

III. Predicate Device

Primary Predicate Device: Fore-Sight Elite Absolute Tissue Oximeter manufactured by CAS Medical Inc. (Now Edwards Lifesciences, *K143675, cleared on April 10, 2015).*

Additional Predicate Devices: HemoSphere Advanced Monitoring Platform (*K201446, cleared on October 1, 2020*).

IV. Device Description

Device Description:

The FORE-SIGHT ELITE Absolute Tissue Oximeter measures hemoglobin under the sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO_2).

The Fore-Sight Elite Monitor is used together with the preamplifier assembly (cable), and Small, Medium and Large Sensors.

The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The Fore-Sight algorithm determines the StO_2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four Sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery pack. A touchscreen user interface allows configuration of the oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB and RS-232.

V. Indications for Use:

Note: the indication for Use statements are identical for the previously cleared technology (*K143675, cleared on April 10, 2015*).

FORE-SIGHT ELITE Absolute Tissue Oximeter

The non-invasive Fore-Sight Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

- When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 Kg.

- When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥ 3 Kg.

- When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects < 8 Kg and non-cerebral use on pediatric subjects < 5 Kg.

Intended Use: The non-invasive Fore-Sight Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced-flow or no-flow ischemic states.

The measured parameter for the Fore-Sight Elite Absolute Tissue Oximeter is listed below.

Parameter	Description	Fore-Sight Elite Sensor Size	Patient Population	Hospital Environment
StO_2	Tissue Oximetry	Large	Adult only	Operating Room, Intensive Care Unit, Emergency Room
		Medium	Pediatric	
		Small	Pediatric	
		Non-Adhesive Small	Pediatric	

VI. Comparison of Technological Characteristics with the Predicate Devices:

The existing FORE-SIGHT ELITE Absolute Tissue Oximeter (*K143675, cleared April 10, 2015*), which is the primary predicate for this submission consists of the Fore-Sight Elite Monitor that contains the algorithm and software for tissue oximetry.

The subject and predicate devices are the same with the exception of the following modifications:

- Algorithm update: The algorithm for determining StO_2 was updated to the same algorithm that has been recently cleared in the secondary predicate, the HemoSphere Advanced Platform (*K201446, cleared on October 1, 2020*). There are no new features with the algorithm update, and the subject device has the same clinical accuracy when compared to the secondary predicate.

  The difference between the StO_2 algorithm of the subject and primary predicate device (*K143675 cleared April 10, 2015*) is that the algorithm has been made more robust to better handle sensor disruption scenarios caused by user or environmental factors. It has been made more dynamic for pediatric applications by increasing StO2 responsiveness.

- Cybersecurity: Cybersecurity updates to the FORE-SIGHT ELITE Absolute Tissue Oximeter include further protection of the

monitor against brute force attack and enforcement to update the password for application-level Biomed account.

- General Monitor Operation Enhancements: Serial Communication improvements, improvement of sound playback for medium and low alarms, and minor bug fixes.

- Graphical User Interface Modifications: The graphical user interface (GUI) is being updated specifically to include the StO_2 option in the Reference Alarm Setting Limits pop-up menu. Previously this option was only accessible through a series of steps. It is now also available in a one-step action. Additional changes to the GUI include the forced password reset pop-up as part of the cybersecurity update and added system message that indicates "limits based on StO2" on the Oximeter display.

- Operator's Manual update: is being updated to include and address the modifications that are the subject of this 510(k) premarket notification as well as add Edwards branding and contact information.

Performance Data (Bench and/or Clinical):

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

Usability Study

Usability study was conducted on the FORE-SIGHT ELITE Absolute Tissue Oximeter per FDA's guidance document "Applying Human Factors and Usability Engineering to Medical Devices" to investigate primary operating functions and critical tasks of the updated system for any usability issues that may lead to patient or user harm.

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.

System Verification (Non-Clinical Performance):

Completion of all verification and validation activities demonstrated that the subject device meets its predetermined design and performance specifications. Verification activities performed confirmed that the algorithm upgrade did not adversely affect the safety and effectiveness of the subject device.

The measured StO_2 parameter was tested using a bench simulation. Additionally, verification of each system requirement was tested after upgrading to the latest algorithm version to verify safety and effectiveness of the subject device. All tests passed.

Software Verification

Software 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". Software was tested at a sub-system level to ensure the safety of the device. All tests passed.

Conclusions

Overall Conclusion:

The technological characteristics of the predicate and the subject device are identical. The FORE-SIGHT ELITE Absolute Tissue Oximeter has successfully passed performance testing, including the software verification and validation, and bench studies. As such, the FORE-SIGHT ELITE Absolute Tissue Oximeter, including the modifications for the platform is substantially equivalent to the legally marketed predicates.