August 18, 2023

Edwards Lifesciences, LLC
Jennifer Wilbur
Director, Regulatory Affairs Program Management
1 Edwards Way
Irvine, California 92614

Re: K230579
Trade/Device Name: Smart Wedge algorithm
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 14, 2023
Received: July 14, 2023

Dear Jennifer Wilbur:

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)*
K230579

Device Name
Smart Wedge algorithm

Indications for Use *(Describe)*
When used in combination with a Swan-Ganz catheter connected to a pressure cable and pressure transducer, the Edwards Lifesciences Smart Wedge algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge algorithm 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 Smart Wedge algorithm parameters.

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

I. Submitter		
Sponsor	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Establishment Registration Number	2015691	
Contact Person	**Primary Contact** Jennifer Wilbur Director, Regulatory Affairs Program Management One Edwards Way Irvine, CA 92614 Telephone: (949) 756-4436 Email: jennifer_wilbur@edwards.com	**Secondary Contact** Karen Clement Sr. Director, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250-4746 Email: Karen_Clement@edwards.com
Date Prepared	July 14, 2023	
II. Device Information		
Trade Name	Smart Wedge algorithm	
Common Name	Pulmonary Artery Occlusion Pressure (PAOP)	
Regulation Number/ Regulation Name	21 CFR 870.1425 / Computer, Diagnostic, Programmable	
Product Code	DQK	
Regulation Class	Class II	
III. Predicate Device		
Predicate Device	The GE CARESCAPE B650 Patient Monitor (K213181, cleared April 13, 2022) manufactured by GE Healthcare Finland Oy, and its pulmonary artery occlusion pressure measurement are being utilized for substantial equivalence as a predicate to the Smart Wedge algorithm in terms of similar technology (principles of operation, functionality and performance) and same/similar indications/intended use.	

IV. Device Description	
Device Description	The Smart Wedge algorithm is designed to provide the value at end-expiration of the pulmonary artery occlusion pressure (PAOP) signal, also called pulmonary wedge pressure, pulmonary capillary wedge pressure (PCWP), or pulmonary artery wedge pressure (PAWP), and to assess the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge algorithm is intended to be used with a Swan-Ganz pulmonary artery catheter connected to a pressure cable and pressure transducer.
V. Indications for Use and Intended Use	
Indications for Use	When used in combination with a Swan-Ganz catheter connected to a pressure cable and pressure transducer, the Edwards Lifesciences Smart Wedge algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge algorithm 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 Smart Wedge algorithm parameters.
Intended Use	The Smart Wedge algorithm is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. The Smart Wedge algorithm is intended to measure and provide accurate pulmonary artery occlusion pressure and to assess the quality of the pulmonary artery occlusion pressure measurement.
VI. Comparison of Technological Characteristics with Predicate Device	
Comparison to Predicate Device	The subject device and predicate devices are based on the following same technological elements: **Hemodynamic Parameters & Technological Characteristics**: • The subject device and predicate device (GE CARESCAPE B650 Patient Monitor, K213181, cleared April 13, 2022) both measure and provide pulmonary artery pressure, have software and provide flag/message outputs. • The subject device and predicate device (GE CARESCAPE B650 Patient Monitor, K213181, cleared April 13, 2022) both measure and provide pulmonary artery occlusion pressure.

	Accessories/Components: • The subject device and predicate device (GE CARESCAPE B650 Patient Monitor, K213181, cleared April 13, 2022) both obtain a pressure waveform measurement from a commercially available pulmonary artery catheter connected to a pressure cable and pressure transducer to obtain a pulmonary artery pressure waveform measurement. **Intended Use/Indications for Use:** • The subject device and predicate device (GE CARESCAPE B650 Patient Monitor, K213181, cleared April 13, 2022) both have similar intended use/indications for use. o The subject device has the same indications/intended purpose as the predicate with respect to its use by trained clinicians in a healthcare environment and with respect to the hemodynamic monitoring of invasive pressure in adult patients. The following technological differences exist between the subject and predicate device: **Algorithm Modifications**: • The subject Smart Wedge algorithm provides the following functional and safety enhancements over the predicate (GE CARESCAPE B650 Patient Monitor, K213181, cleared April 13, 2022): ➢ PAOP Measurement: The subject Smart Wedge algorithm will not only display a PAOP measurement like the predicate device, but it will also display PAOP within mean absolute error < 4 mmHg accuracy. ➢ Measurement of PAOP Quality: The subject Smart Wedge algorithm includes a new measurement as to the quality of the PAOP reading. This quality measurement is provided simultaneously with the PAOP value. ➢ Additional Flag Outputs/Messages: The subject Smart Wedge algorithm includes additional safety flag outputs/messages for "no wedge detected" and "wedge too long" and an additional "artifact detected" flag output/message. The subject device continues to have the same overall intended use/indications and fundamental scientific technology.

Device Testing / Performance Data

The following verification activities were performed in support of a substantial equivalence determination for the Smart Wedge algorithm and predicate devices and to ensure safety and effectiveness of the Smart Wedge algorithm:

Software Verification:
Software verification was performed in accordance with IEC 62304:2006/A1:2016, *Medical device software – Software life cycle processes*, ISO 14971:2019, *Medical devices, Applications of risk management to medical devices*, 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 FDA's Guidance for Industry and FDA Staff, *General Principles of Software Validation* (issued January 11, 2002). The Smart Wedge algorithm was tested at the algorithm level to ensure the safety of the device. The verification of the Smart Wedge algorithm was performed using waveforms retrospectively collected from ICU and OR patients. The basis for determination of substantial equivalence included retrospective clinical validation testing as shown in Table 1 for PAOP identification and Table 2 for PAOP measurement, with the references (i.e., consensus) being independent annotations by three experienced health care providers (HCPs). Results for the Smart Wedge algorithm met or exceeded predicate device performance.

Table 1: Performance Results of PAOP Identification
Data presented as average value with 95% confidence interval (CI). PPV: positive predictive value, NPV: negative predictive value.

Smart Wedge Algorithm Parameter	Method Used to Obtain Reference Value (Consensus)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
PAOP Identification (225 PAP waveforms from 129 patients)	Mode of three HCP annotations	100 [100,100]	96 [92, 100]	95 [89, 99]	100 [100, 100]

Table 2: Performance Results of PAOP Measurements
Data presented as average value with 95% confidence interval (CI). MAE: mean absolute error, Std: standard deviation.

Smart Wedge Algorithm Parameter	Method Used to Obtain Reference Value (Consensus)	MAE (mmHg)	Bias (mmHg)	Std (mmHg)	Correlation r
PAOP Measurement (110 PAOP measurements from 59 Patients)	Average PAOP measurement of three HCPs	1.1 [0.8, 1.5]	0.4 [0.1, 0.7]	1.7 [1.4, 2.0]	0.98

Clinical Performance:
No clinical trial was performed in support of the subject 510(k).

Conclusion	**Overall Conclusion:** The subject Smart Wedge algorithm successfully passed all functional and performance testing, including software verification and validation and bench studies. Completion of all performance verification and validation activities demonstrated that the subject device meets its predetermined design and performance specifications. Verification activities performed confirmed that the differences in the features and design did not adversely affect the safety and effectiveness of the subject device. The testing performed demonstrates that the subject Smart Wedge algorithm is substantially equivalent to its legally marketed predicate.