July 12, 2023

Edwards Lifesciences LLC
Omar Becerra
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K231035
Trade/Device Name: FusedCO Algorithm
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: April 10, 2023
Received: April 11, 2023

Dear Omar Becerra:

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 Hetal B. Patel -S

Robert Kazmierski
Acting 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)*
K231035

Device Name
FusedCO algorithm

Indications for Use *(Describe)*
The FusedCO Algorithm when used with Edwards' Swan-Ganz advanced technology pulmonary artery catheter and Acumen IQ sensor is indicated for use in adult critical care patients requiring monitoring of cardiac output and derived hemodynamic parameters in a hospital environment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

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 – FusedCO Algorithm

I. Submitter

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

Establishment Registration Number: 2015691

Contact Person: Omar Becerra
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
omar_becerra@edwards.com
Telephone: (949) 250-1478

Date: July11, 2023

II. Device Information

Device Name: FusedCO Algorithm

Common Name: Cardiac Output Computer

Classification: Programmable Diagnostic Computer, 21 CFR 870.1425

Product Code: DQK, Class II

III. Predicate Device

Predicate Device HemoSphere Advanced Monitoring Platform with HemoSphere Pressure Cable, manufactured by Edwards Lifesciences, K180881 cleared November 18, 2018.

IV. Device Description

Device Description: The FusedCO algorithm is a cardiac output (CO) algorithm available when operating with an Edwards' Swan-Ganz advanced technology pulmonary artery catheter and Acumen IQ sensor. The FusedCO algorithm uses cardiac output signals from a Swan-Ganz advanced technology pulmonary artery catheter and an Acumen IQ sensor (arterial line) to provide a fused cardiac output (FusedCO) and its derived parameters, cardiac index (CI), stroke volume (SV) and stroke volume index (SVI), every 20 seconds.

V. Indications for Use/Intended Use

Indications for Use: The FusedCO algorithm when used with an Edwards' Swan-Ganz advanced technology pulmonary artery catheter and Acumen IQ sensor is indicated for use in adult critical care patients requiring monitoring of cardiac output and derived hemodynamic parameters in a hospital environment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

Intended Use: The FusedCO algorithm is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

The FusedCO algorithm is intended for use with a compatible Edwards Swan-Ganz advanced catheter and Acumen IQ sensors for the monitoring of cardiac output (CO) and derived hemodynamic parameters.

VI. Comparison of Technological Characteristics with the Predicate Device

Comparison to Predicate Device: The HemoSphere Advanced Monitoring Platform (cleared in K180081) was chosen as the predicate device as it shares the same intended use, performance specifications, and has similar technological characteristics as the subject FusedCO algorithm.

The subject and predicate devices are based on the following same intended use and performance specifications:

- Intended use: The subject FusedCO algorithm has the same intended use as the predicate device (K180881), both are intended to provide cardiac output and its derived parameters.
- Performance specifications: The subject FusedCO algorithm has the same performance specifications for the cardiac output measurement as the predicate device (K180881).

The following is the technological difference between the subject device and predicate devices:

- The predicate device provides cardiac output and its derived parameters every 57 seconds based on thermal signals when using a Swan-Ganz advanced technology pulmonary artery catheter, or every 20 seconds based on arterial pressure waveforms when using an Acumen IQ sensor. The FusedCO algorithm further processes the existing data by fusing the cardiac outputs generated by thermal signal from Swan-Ganz advanced technology pulmonary artery catheter and arterial pressure waveform from an Acumen IQ sensor and provides a fused parameter

every 20 seconds. FusedCO algorithm provides a continuous cardiac output with an improved update rate compared to the existing cardiac output using the Swan-Ganz advanced technology pulmonary artery catheter alone.

Performance Data (Bench and/or Clinical):

The following verification activities were performed in support of a substantial equivalence determination for FusedCO algorithm.

Algorithm 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).

The FusedCO algorithm performance was tested to ensure the safety of the device. The verification of the FusedCO algorithm was performed using patient data, including cardiac output from a Swan-Ganz advanced technology pulmonary artery catheter and arterial pressure waveforms, collected retrospectively.

The FusedCO algorithm passed all testing.

Conclusions

Overall Conclusion:

The FusedCO algorithm has the same intended use, performance specifications and similar technological characteristics as the predicate device. The information submitted in this premarket notification demonstrate that the difference in technology does not raise different questions of safety and effectiveness and FusedCO algorithm is as safe and as effective as the predicate device. The FusedCO algorithm has successfully passed functional and performance testing, including software verification and validation and bench studies. The testing performed demonstrates that the FusedCO algorithm is substantially equivalent to its legally marketed predicate.