Edwards LifeSciences, LLC
Anne Lo
Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

June 13, 2019

Re: K191089
Trade/Device Name: Edwards Pressure Cable
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: April 22, 2019
Received: April 24, 2019

Dear Anne Lo:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191089

Device Name
Edwards Pressure Cable

Indications for Use *(Describe)*
The Edwards Pressure Cable when used with an Edwards' pressure monitoring sensor and connected to a compatible monitor, offers continuous assessment of hemodynamic parameters. The Edwards Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. 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.

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SECTION 5 – 510(k) SUMMARY

Edwards Pressure Cable	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Anne Lo
Date Prepared	June 6, 2019
Trade Name	Edwards Pressure Cable
Common Name	Pressure Cable
Classification Name	Programmable diagnostic computer
Regulation Class / Product Code	21 CFR 870.1425/Class II/DQK
Predicate Device	HemoSphere Pressure Cable cleared in the HemoSphere Advanced Platform 510(k) (K180881, cleared November 16, 2018)
Device Description	The Edwards Pressure Cable is a reusable device that connects with a compatible monitor on one end, and an Edwards' pressure monitoring sensor on the other end to continuously measure hemodynamic parameters. The Edwards Pressure Cable acts as a sub-system module to a compatible monitor and has all the electronics, software and algorithms built into the cable to allow for monitoring and calculating patient hemodynamic parameters. Parameters available on the Edwards Pressure Cable include: Continuous cardiac output/continuous cardiac index (CO/CI) Cardiac power output/cardiac power index (CPO/CPI) Central venous pressure (CVP) Diastolic blood pressure (DIA) Mean arterial blood pressure (MAP) Mean pulmonary artery blood pressure (MPAP) Stroke volume/stroke volume index (SV/SVI) Systemic vascular resistance/systemic vascular resistance index (SVR/SVRI) Stroke volume variation (SVV) Systolic blood pressure (SYS)
Indications for Use/Intended Use	The Edwards Pressure Cable when used with an Edwards' pressure monitoring sensor and connected to a compatible monitor, offers continuous assessment of hemodynamic parameters. The Edwards Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

Comparison to Predicate Device

Differences Include:

- Revision to the intended use and indications for use statement for the Edwards Pressure Cable to allow compatibility with third party monitors. These revisions do not change the inherent intended use and indications for use.
- Revision to the labeling to remove the specific reference to the HemoSphere Advanced Monitoring System

Table 1: Device Comparison of the Predicate HemoSphere Pressure Cable with Subject Edwards Pressure Cable

Features	Predicate Device	Subject Device
Indications for Use	The HemoSphere advanced monitor when used with the HemoSphere Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, Acumen IQ sensor, FloTrac IQ sensor, and TruWave DPT indications for use statements for information on target patient population specific to the sensor/transducer being used.	The Edwards Pressure Cable when used with an Edwards' pressure monitoring sensor and connected to a compatible monitor, offers continuous assessment of hemodynamic parameters. The Edwards Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.
Intended Use	The HemoSphere advanced monitoring platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. The HemoSphere advanced monitoring platform is intended for use with compatible Edwards oximetry and Swan-Ganz catheters and pressure monitoring sensors and catheters. A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere Pressure Cable or connected HemoSphere Pressure Cable and oximetry cable are listed in table 2 and 3.	The Edwards Pressure Cable is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. The Edwards Pressure Cable is intended for use with compatible monitors, and Edwards pressure monitoring sensors and compatible catheters.

Performance Data

No new testing was performed since the subject and predicate devices are identical and have similar intended use and indications for use. The Edwards Pressure Cable leverages the testing for the predicate HemoSphere Pressure Cable (HemoSphere Advanced Platform, K180881, cleared November 16, 2018). The testing was performed in compliance with the following standards:

- IEC 60601-1:2005+A1:2012 *Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2 *Medical Electrical Equipment, Part 1-2: General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests*

	• IEC 60601-1-6 *Medical Electrical Equipment, Part 1-6: General Requirements for Safety and Essential Performance- Collateral Standard: Usability* • IEC 60601-1-8 *Medical Electrical Equipment, Part 1-8: General Requirements for Basic Safety and Essential Performance- Collateral Standard: General Requirements, Tests, and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems* • IEC 62304 *Medical Device Software- Life Cycle Processes* • IEC 62366 *Medical Devices- Application Usability Engineering to Medical Devices* Software Verification: The Edwards Pressure Cable is considered software with a Moderate Level of Concern. 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". The testing requirements for the predicate HemoSphere Pressure Cable was tested and passed at a sub-system level to ensure the safety of the device. This testing is applicable to the subject Edwards Pressure Cable. All testing for Electrical Safety and Electromagnetic Compatibility (EMC) and Software Verification testing being leveraged for the subject Edwards Pressure Cable passed. All performance testing leveraged for the subject Edwards Pressure Cable was previously submitted in the predicate 510(k) that included the HemoSphere Pressure Cable (HemoSphere Advanced Monitoring Platform), (K180881, cleared November 16, 2018).
Conclusion	The subject Edwards Pressure Cable is identical to the predicate HemoSphere Pressure Cable and has similar intended use and indications for use. Therefore, it is substantially equivalent.