September 21, 2023

Edwards Lifesciencess LLC
Anne Lo
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K231248
Trade/Device Name: Swan-Ganz Catheters, FloTrac sensors, ClearSight finger cuffs, HemoSphere Advanced Monitoring Platform
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-Directed Catheter
Regulatory Class: Class II
Product Code: DYG, DQO, DRS, DXN, DQK
Dated: April 30, 2023
Received: May 1, 2023

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,

Robert T. Kazmierski -S

for

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)*
K231248

Device Name
Swan-Ganz catheters, FloTrac sensors, ClearSight finger cuffs, and HemoSphere Advanced Monitoring Platform

Indications for Use *(Describe)*

Swan-Ganz catheters- Indications for Use:
The Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

Models 096F6, 096F6P, TS105F5, 132F5, 131F7, 131F75P, 831F75, 831F75P, 834F75, and 834F75P are intended for adult and pediatric patients:
The Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of critically ill adult and pediatric patients ≥12 years of age including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

FloTrac sensors- Indications for Use:
The FloTrac sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output. They are intended to be used in adult patients.

Models MHD6, MHD8, MHD65, and MHD85 are intended for adult and pediatric patients:
The FloTrac sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output. The FloTrac sensor is indicated for use in adult and pediatric patients ≥12 years of age.

ClearSight finger cuffs- Indications for Use:
The Acumen IQ are indicated for patients over 18 years of age to non-invasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform or HemoSphere advanced monitoring platform.

The ClearSight finger cuffs are indicated for adult and pediatric patients ≥12 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform or HemoSphere advanced monitoring platform.

HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module- Indications for Use:
The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) 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. Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

HemoSphere Advanced Monitor with HemoSphere Pressure Cable- Indications for Use:
The HemoSphere advanced monitor when used with the HemoSphere pressure cable is indicated for use in adult and pediatric 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 of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, Acumen IQ sensor, and TruWave DPT indications for use statements for information on target patient populations specific to the sensor/transducer being used.

The Edwards Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI™ feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI™ feature 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 Acumen Hypotension Prediction Index (HPI) parameter.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

HemoSphere Advanced Monitor with HemoSphere ClearSight Module - Indications for Use:
The HemoSphere advanced monitor when used with the HemoSphere ClearSight module, pressure controller and a compatible Edwards finger cuff are indicated for adult and pediatric patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the noninvasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

Refer to the ClearSight finger cuff and Acumen IQ finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

The Edwards Acumen Hypotension Prediction Index (HPI) feature provides the clinician with physiological insight into patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature 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 Acumen Hypotension Prediction Index (HPI) parameter.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary- Swan-Ganz catheters, FloTrac sensors, ClearSight finger cuffs, HemoSphere Advanced Monitoring Platform

510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Contact Person	**Primary Contact** Anne Lo Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250-3386 Fax: (949) 809 - 2954 Email: Anne_Lo@edwards.com	**Secondary Contact** Karen O'Leary Sr. Director, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 610-9179 Fax: (949) 809 - 2954 Email: Karen_OLeary@edwards.com
Date Prepared	September 19, 2023	
Trade Name	Swan-Ganz catheters FloTrac sensors ClearSight finger cuffs HemoSphere Advanced Monitoring Platform	
Common Name	Swan-Ganz catheters: Cardiovascular Diagnostic Catheters FloTrac sensors: Dual Disposable Pressure Transducer ClearSight finger cuffs: Non-Invasive Blood Pressure Measurement System HemoSphere Advanced Monitoring Platform: Programmable Diagnostic Computer	
Regulation Number/ Regulation Name	Swan-Ganz catheters: 21 CFR §870.1240, 21 CFR §870.1200 FloTrac sensors: 21 CFR §870.2850 ClearSight finger cuffs: 21 CFR §870.1130 HemoSphere Advanced Monitor: 21 CFR §870.1425, 21 CFR §870.1230, 21 CFR §870. 2210, 21 CFR §870. 1130, 21 CFR §870.2770	
Product Code	Swan-Ganz catheters: DYG, DQO FloTrac sensors: DRS ClearSight finger cuffs: DXN HemoSphere Advanced Monitor: DQK, DQE, QAQ, DXN, DSB	
Regulation Class	Class II	
Predicate Device	Swan-Ganz catheters: K160084, cleared on May 03, 2016 FloTrac sensors: K152980, cleared on January 19, 2016 ClearSight finger cuffs: K190130, cleared on June 21, 2019 HemoSphere Advanced Monitoring System: K221833, cleared on Nov 7, 2022	
Device Description	**Swan-Ganz Catheters:** The Swan-Ganz catheters are flow-directed pulmonary artery catheters used to monitor hemodynamic pressures. The Swan-Ganz thermodilution catheters provide diagnostic information to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer.	

	FloTrac Sensors: The FloTrac sensor is a sterile, single use kit that monitors pressures when attached to pressure monitoring catheters. When connected to a compatible monitor, the FloTrac sensor minimally-invasively measures cardiac output and key hemodynamic parameters, which assist the clinician in assessing the patient's physiologic status and support clinical decisions related to hemodynamic optimization. The disposable sterile cable, with a red-connector interfaces, exclusively with an Edwards cable that is specifically wired for the pressure monitor being used. The disposable sterile cable, with a green-connector interfaces, exclusively with the Edwards cables for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware. The FloTrac sensor has a straight, flow-through design across the pressure sensors with an integral flush device. **ClearSight finger cuffs:** The ClearSight finger cuffs, when used with an appropriate Edwards monitoring system, provide continuous, noninvasive hemodynamic monitoring. The ClearSight finger cuffs utilize the volume-clamp method to measure blood pressure with an inflatable bladder wrapped around the middle phalanx of the finger. **HemoSphere Advanced Monitor Platform:** The HemoSphere Advanced Monitoring Platform was designed to simplify the customer experience by providing one platform with modular solutions for their hemodynamic monitoring needs. The user can choose from the available optional sub-system modules or use multiple sub-system modules at the same time. This modular approach provides the customer with the choice of purchasing and/or using specific monitoring applications based on their needs. Users are not required to have all of the modules installed at the same time for the platform to function.
Indications for Use/Intended Use	**Swan-Ganz catheters:** The Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure. Models 096F6, 096F6P, TS105F5, 132F5, 131F7, 131F7P 831F75, 831F75P, 834F75, and 834F75P are intended for adult and pediatric patients: The Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of critically ill adult and pediatric patients ≥ 12 years of age including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure. **FloTrac sensors:** The FloTrac sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output. They are intended to be used in adult patients. Models MHD6, MHD8, MHD65, and MHD85 are intended for adult and pediatric patients: The FloTrac sensor is indicated for use in intravascular pressure monitoring. It is also

	indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output. The FloTrac sensor is indicated for use in adult and pediatric patients ≥ 12 years of age. **ClearSight finger cuffs:** The Acumen IQ are indicated for patients over 18 years of age to non-invasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform or HemoSphere Advanced Monitoring Platform. The ClearSight finger cuffs are indicated for adult and pediatric patients ≥ 12 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform or HemoSphere Advanced Monitoring Platform. **HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module:** The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) 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. Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used. Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population. **HemoSphere Advanced Monitor with HemoSphere Pressure Cable (compatible with FloTrac sensors):** The HemoSphere advanced monitor when used with the HemoSphere pressure cable is indicated for use in adult and pediatric 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 of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, Acumen IQ sensor, and TruWave DPT indications for use statements for information on target patient populations specific to the sensor/transducer being used. The Edwards Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI™ feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI™ feature 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 Acumen Hypotension Prediction Index (HPI) parameter. Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population. **HemoSphere Advanced Monitor with ClearSight Module:** The HemoSphere advanced monitor when used with the HemoSphere ClearSight module, pressure controller and a compatible Edwards finger cuff are indicated for adult and

	pediatric patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the noninvasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters. Refer to the ClearSight finger cuff and Acumen IQ finger cuff indications for use statements for information on target patient population specific to the finger cuff being used. The Edwards Acumen Hypotension Prediction Index (HPI) feature provides the clinician with physiological insight into patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature 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 Acumen Hypotension Prediction Index (HPI) parameter. Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.
Comparison to Predicate Device	**The subject devices of this Traditional 510(k) are identical to the predicate devices cleared in the above listed 510(k)s in terms of the design, performance specifications, technological characteristics, software, hardware, and algorithm with the exception of the indications for use and the labeling. Differences in the indications for use to add pediatric patient population do not raise any new concerns of safety and effectiveness.** The clinical data presented in this 510(k) demonstrates the performance of hemodynamic parameters expanded to pediatric patients ≥ 12 years of age for Swan-Ganz catheters, FloTrac sensors, ClearSight finger cuffs and compatible HemoSphere sub-system modules are consistent and within predefined acceptance criteria. The data demonstrate the performance in the expanded pediatric population ≥ 12 years of age and is substantially equivalent to their respective predicate devices for adult patient population ≥ 18 years of age.
Device Verification and Validation	**The subject devices were evaluated in the target pediatric population in a clinical study and results of the study demonstrate that devices can be used in that population with no issues of safety and effectiveness.**
Conclusion	**The data provided demonstrates that use of the FloTrac, ClearSight and Swan-Ganz technologies is safe and effective in measuring cardiac output in pediatric subjects ≥ 12 years of age, with similar performance to an adult population. The subject devices are substantially equivalent to their respective predicate devices.**