December 9, 2022

Edwards Lifesiences, LLC
Michelle Ducca
Manager, Regulatory Affairs
1 Edwards Way
Irvine, California 92614

Re: K222117
Trade/Device Name: Swan-Ganz IQ Pulmonary Arterial catheter
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-Directed Catheter
Regulatory Class: Class II
Product Code: DYG
Dated: November 4, 2022
Received: November 7, 2022

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,

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)*
K222117

Device Name
Swan-Ganz IQ Pulmonary Arterial Catheter

Indications for Use *(Describe)*
The primary indications for the Swan-Ganz IQ Pulmonary Arterial catheter includes:
• Acute heart failure
• Severe hypovolemia
• Complex circulatory situations
• Medical emergencies
• Adult respiratory distress syndrome
• Gram negative sepsis
• Drug intoxication
• Acute renal failure
• Hemorrhagic pancreatitis
• Intra and post-operative management of high risk patients
• History of pulmonary or cardiac disease
• Fluid shifts (e.g., extensive intra-abdominal operations)
• Management of high-risk obstetrical patients
• Diagnosed cardiac disease
• Toxemia
• Premature separation of placenta
• Cardiac output determinations
• Differential diagnosis of mitral regurgitation and ventricular septal rupture
• Diagnosis of cardiac tamponade

Secondary indications include the following:
• Blood Sampling
• Infusion of saline and dextrose solutions

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 – Swan-Ganz IQ catheter model AIQSGF8

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Michelle Ducca Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 michelle_ducca@edwards.com Telephone: (949) 250-4113
Date:	July 15, 2022
Trade Name:	Swan-Ganz IQ catheter *(subject)*
Common Name:	Cardiovascular Diagnostic Catheters
Classification Name:	Flow-directed catheter 21 CFR 870.1240
Product Code:	DYG, Class II
Predicate Device(s):	The Edwards Swan-Ganz catheters (Models 777F8 and 780F75M), manufactured by Edwards Lifesciences, K160084 cleared May 3, 2016, is being utilized for substantial equivalence due to the same basic device functionality, similar indications and intended use, labeling and principle of operation as the subject device.
Device Description:	The Edwards Swan-Ganz catheters are used to monitor the hemodynamic status of critically ill and injured patients. The existing catheters give clinicians the ability to measure right heart pressures, pulmonary artery occlusion pressure ("wedge"), sample mixed venous blood from the pulmonary artery, as well as measure cardiac output through thermodilution when used with a bedside physiologic monitor and pressure transducers. The Edwards Swan-Ganz product line is comprised of Standard (Base) and Advanced Technology monitoring catheters. The standard Swan-Ganz catheter

measures: right heart pressures, thermodilution cardiac output (room temperature and chilled) and provides a mechanism for pulmonary artery blood sampling for laboratory analysis.

The subject Swan-Ganz IQ catheter combines features from the existing Advanced catheter design (model 777F8) and the Paceport catheter design (model 780F75M). Using the 777F8 model as the base design, the new catheter modifies the design to remove the thermal filament functionality and replaces it with an additional port which will allow for pressure monitoring at the right ventricular level. The RV port is utilized just like the Swan-Ganz Paceport Oximetry catheter model 780F75M.

Just like the existing advanced catheters, the Swan-Ganz IQ catheter provides the same functionality as the standard and Advanced Technology Swan-Ganz catheters by providing the ability to continuously monitor the patient's balance between oxygen delivery and consumption as well as the ability to help investigate the root cause of an imbalance through analysis of the components of stroke volume (preload, afterload, and contractility).

Indications for Use:

Indications for Use – Swan-Ganz IQ catheter:

The primary indications for the Swan-Ganz IQ Pulmonary Arterial catheter includes:

- Acute heart failure
- Severe hypovolemia
- Complex circulatory situations
- Medical emergencies
- Adult respiratory distress syndrome
- Gram negative sepsis
- Drug intoxication
- Acute renal failure
- Hemorrhagic pancreatitis
- Intra and post-operative management of high risk patients
- History of pulmonary or cardiac disease
- Fluid shifts (e.g., extensive intra-abdominal operations)
- Management of high-risk obstetrical patients
- Diagnosed cardiac disease
- Toxemia
- Premature separation of placenta
- Cardiac output determinations
- Differential diagnosis of mitral regurgitation and ventricular septal rupture
- Diagnosis of cardiac tamponade

Secondary indications include the following:

- Blood Sampling

• Infusion of saline and dextrose solutions

Intended Use: **Intended Use- Swan-Ganz IQ catheter**:

The Swan-Ganz IQ catheter (model AIQSGF8) is for use in patients who require hemodynamic monitoring. It is intended to be used in combination with clinical pressure monitoring, equipment to measure right heart and pulmonary artery pressures, and with a compatible cardiac output computer to measure intermittent cardiac output. Model AIQSGF8 also measures mixed venous oxygen saturation.

Comparison to Predicate Device:

The following technological similarities exist between the subject and predicate devices:

The scientific technology and materials of the subject device are unchanged from the legally marketed predicate devices. Both the subject and predicate devices provide the same hemodynamic pressure monitoring and provides intermittent cardiac output, mixed venous oxygen saturation and stroke volume. The modified Swan-Ganz catheter device is identical to the predicate devices in terms of indications for use and has the same overall intended use without the thermodilution functions.

The following technological differences exist between the subject and predicate devices:

- Thermal filament removed: The currently cleared predicate catheter model 777F8 (K160084 cleared May 3, 2016) has been modified to remove the components relating to the thermal filament including white heater extension tubing.
- Additional port: An additional port has been implemented to replace the thermal filament with extension tubing (violet) to allow for pressure monitoring from the right ventricular level. The same RV port for pressure monitoring is already available in the existing predicate device model 780F75M (K160084 cleared May 3, 2016).
- Addition of y-connector as tether point on thermistor extension tubing (yellow) along with short white extension tubing for EEPROM connector.

These differences are not a fundamental change in scientific technology and have no impact to the indications for use or overall intended use.

The existing Swan-Ganz catheter product line includes IFU's for the Pacing, Base and Advanced models. An additional separate IFU for the Swan-Ganz IQ catheter model will be added to the Swan-Ganz product line, which includes the same Indication for Use and the same overall Intended Use as the predicate

devices (K160084), an updated image, and removal of thermal filament functionality and associated bolus thermodilution parameters (CCO, EDV, RVEF) in the Instructions for Use.

Performance Data: The Swan-Ganz IQ catheter has successfully passed functional and performance testing including packaging, shelf life, sterilization, biocompatibility and bench testing, which included frequency response testing, pressure tubing pull testing and lumen burst pressure testing per ISO 10555-1:2013 and IEC 60601:2015 Amd.1:2020.

Conclusions The subject Swan-Ganz IQ catheter has successfully passed all functional and performance testing including verification and validation, sterilization, shelf life, biocompatibility and bench testing. 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 Swan-Ganz IQ (model AIQSGF8) is substantially equivalent to the predicate Swan-Ganz catheter predicate devices models 777F8 and 780F75M (K160084, cleared May 3, 2016).