February 16, 2020

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

Re: K193466
Trade/Device Name: Swan-Ganz Flow-Directed Monitoring Catheters- Double and Triple Lumen

Swan-Ganz- Thermodilution, True Size

Swan-Ganz
Polymer Blend True Size ControlCath Thermodilution catheters, and Polymer Blend True Size Torque Support Thermodilution catheter

Swan-Ganz Oximetry TD catheter

Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-Directed Catheter
Regulatory Class: Class II
Product Code: DYG, DQE, DQO
Dated: December 12, 2019
Received: December 16, 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,

Jessica Paulsen
Division 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

510(k) Number: K193466

Device Name: Swan-Ganz Flow-Directed Monitoring catheters- Double and Triple Lumen

Models: 111NX7P, S111NX7, T111NX7P, 123NX6P, T123NX6, 110NX5P, 114NX7P

Indications For Use:
Swan-Ganz flow-directed monitoring catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

Device Name: Swan-Ganz- Thermodilution Catheters, True Size

Models: 131NX7P, 131VNX7P, 141NX7P, 143TNX7, 151NX7, 096NX6P, TS105NX5, 132NX5

Indications For Use:
Swan‑Ganz thermodilution catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions.

The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

Device Name: Swan-Ganz
Polymer Blend True Size ControlCath Thermodilution catheters, and
Polymer Blend True Size Torque Support Thermodilution catheter

Models: C144NX7, S144NX7, C145NX6, T173NX6

Indications For Use:
ControlCath thermodilution catheters and Torque Support Thermodilution catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions.

The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

Device Name: Swan-Ganz Oximetry TD catheter

Model: 631NX55

Indications For Use:
Swan-Ganz oximetry TD catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions.

For 631NX55, the distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 801 Subpart C)

K193466 - 510(k) SUMMARY

Swan-Ganz Base and Advanced catheters (5F-7F size) with SEBS balloons	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Anne Lo Specialist, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 –3386 Fax: (949) 809 –7779
Date Prepared	December 12, 2019
Trade Name	Swan-Ganz Flow-Directed Monitoring catheters- Double and Triple Lumen Swan-Ganz- Thermodilution Catheters, True Size Swan-Ganz Polymer Blend True Size ControlCath Thermodilution catheters, and Polymer Blend True Size Torque Support Thermodilution catheter Swan-Ganz Oximetry TD catheter
Common Name	Cardiovascular Diagnostic Catheters
Classification Name	Flow-directed catheter (21 CFR 870.1240) Fiberoptic oximeter catheter (21 CFR 870.1230) Diagnostic intravascular catheter (21 CFR 870.1200)
Regulation Class / Product Code	Class II DYG, DQE, DQO
Primary Predicate Device	K160084- Swan Ganz catheters
Reference Predicate Device	K001063- Swan-Ganz Synthetic ControlCath Thermodilution catheters
Device Description	The Swan-Ganz catheters are cardiovascular diagnostic catheters intended for use on critical care patients. Swan-Ganz catheters are used to monitor the hemodynamic status of critically ill and injured patients. The 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. The subject Edwards Swan-Ganz product line is comprised of Base and Advanced Technology monitoring catheters. The Base 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. In addition to providing most of the same functionality as the Base models, the Advanced Swan-Ganz catheters provide the ability to continuously monitor the patient's mixed venous oxygen saturation, the balance between oxygen delivery and consumption, when used with an Edwards Lifesciences oximetry monitor or compatible bedside module system. It also monitors cardiac output with a compatible cardiac output computer.
Indications for Use/Intended Use	**The intended use for the Base Swan Ganz catheters are identical:** The Swan-Ganz Catheters are cardiovascular catheters intended for use on critical care patients. **The Indications for Use are slightly different among the different Base models:** **Swan Ganz Flow-Directed Monitoring catheters- Double and Triple Lumen** Swan-Ganz flow-directed monitoring catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions. **Swan-Ganz Thermodilution Catheters, True Size** Swan-Ganz thermodilution catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

	Swan-Ganz **Polymer Blend True Size ControlCath Thermodilution catheters, and Polymer Blend True Size Torque Support Thermodilution catheter** ControlCath thermodilution catheters and Torque Support Thermodilution catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction. **The intended use for the Advanced Swan Ganz catheters is the same as the Base Swan Ganz catehters with the addition of hemodynamic monitoring capabilities.** Swan-Ganz catheters are intended to be used with compatible critical care patient monitors, for monitoring the hemodynamic condition of a critically ill patient. **Swan-Ganz Oximetry TD catheter** Swan-Ganz oximetry TD catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions. For 631NX55, the distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.
Comparative Analysis	Technological Modifications: • Change balloon material from latex to a non-latex Styrene Ethylene Butylene Styrene (SEBS) material. Additional device modifications were made that complement the change in balloon material to SEBS as listed below: • Add an adhesive primer to the balloon bonding process to ensure balloon bond strength. • Modify the tip dimension and balloon bonding process for model 110NX5P to be the same as other 5F and 6F catheters.

	• Modify the inflation volume of the 5F and 6F catheters to maintain the same inflation diameter as the predicate devices. No changes were made to the catheter body; the device modifications are limited to the balloon and catheter tip. Labeling Modifications: • IFU modifications as a result of the technological modifications made to the subject device. • Updates to labeling that are administrative. • Updates which provide consistency across subject device labeling and clarity for users.
Functional/ Safety Testing	The Swan-Ganz Base and Advanced catheters (5F-7F size) with SEBS balloons are identical to the predicate device in terms of intended use and indications for use. To ensure that the Swan-Ganz Base and Advanced catheters (5F-7F size) with SEBS balloons are substantially equivalent to the predicate devices, the following testing was performed: • Functional testing of the catheter balloon to show performance was not affected. • Biocompatibility testing in accordance to ISO 10993-1:2018 and the FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.* • Sterilization testing in accordance to ISO 11135:2014 *Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routing control of a sterilization process for medical devices* and the FDA Quality System Regulation, 21CFR820.30. • Usability and human factors testing in accordance to IEC 62366:2015 and the FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices.* The Swan-Ganz Base and Advanced catheters (5F-7F size) with SEBS balloons have successfully passed functional, biocompatibility testing, usability and human factors, performance testing and bench studies, demonstrating that the subject device is substantially equivalent to the predicate device.
Conclusion	The Swan-Ganz Base and Advanced catheters (5F-7F size) with SEBS balloons have been shown to be substantially equivalent to the predicate device for their intended use.