DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 3, 2016

Edwards Lifesciences, LLC
Mugdha Dongre
Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K160084
Trade/Device Name: Swan Ganz Catheters
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-Directed Catheter
Regulatory Class: Class II
Product Code: DYG, DQE, DQO, KRA
Dated: March 21, 2016
Received: March 22, 2016

Dear Mugdha Dongre:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Shawn W. Forrest -S
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for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160084

Device Name
Swan-Ganz Catheters

Indications for Use *(Describe)*
Device Name: Swan-Ganz Flow-Directed Monitoring catheters- Double and Triple Lumen
Indications For Use:
Models: 111F7, 111F7P, S111F7, T111F7, 123F6, 123F6P, T123F6, 110F5, 116F4, 115F7, 115F7P, 114F7 and 114F7P
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, VIP and VIP+, True Size
Indications For Use:
Models: 131F7, 131F7P, 131VF7P, 141F7, 143TF7, 151F7, 831F75, 831F75P, 831VF75P, 834F75, 096F6, 096F6P, TS105F5 and 132F5
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- Thermodilution Paceport catheters, Thermodilution A-V Paceport catheters
Indications For Use:
Model 931F75
The Swan-Ganz thermodilution Paceport catheters (Model 931F75) are used for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The Paceport catheter (Model 931F75) may also be used for standby temporary ventricular pacing.
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.
Model 991F8
The Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) is indicated for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions. The A-V Paceport catheter (Model 991F8) is also indicated for standby temporary ventricular, atrial, or A-V sequential pacing using the Model D98100 Chandler Transluminal V-pacing probe and/or Model D98500 A-pacing probe. 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, Synthetic ControlCath Thermodilution Catheters, Polymer Blend True Size Torque Support Thermodilution catheter
Indications For Use:
Models: C144F7, S144F7, C145F6N, C146F7 and S9FC146F7
ControlCath 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.
Model: T173F6
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 Continuous Cardiac Output Thermodilution catheters - CCO Catheters, CCO/SvO2 Catheters, CCO/ SvO2/ VIP Catheters, CCO V CCO/ CEDV Catheters, CCOmbo V CCO/SvO2/CEDV Catheters, CCOmbo V CCO/SvO2/ CEDV/VIP Catheters
Indications For Use:
Models: 139F75, 744F75, 746F8, 177F75N, 774F75 and 777F8
The primary indications for the Swan-Ganz CCO thermodilution catheters include:
• 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
Models with CEDV capabilities are also indicated for volumetric determinations

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

Device Name: Swan-Ganz Continuous Cardiac Output/End Diastolic Volume Thermodilution catheter- CCOmbo EDV CCO/SvO2/EDV/VIP
Indications For Use:
Model: 757F8
The primary indications for the CCOmbo EDV TD catheters include:
• Acute heart failure
• Severe hypovolemia
• Complex circulatory situations
• Medical emergencies
• Adult respiratory distress syndrome
• Gram negative sepsis
• Multi system organ failure
• 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
• Volumetric 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

Device Name: Swan-Ganz Oximetry TD catheter- Oximetry catheters, Oximetry Paceport catheter, VIP Oximetry catheter
Indications For Use:
Models: 631F55N, 780F75M and 782F75M
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.
The oximetry Paceport catheters (model 780F75M) are also indicated for standby temporary ventricular pacing using the model D98100 Chandler transluminal V-pacing probe. For all models, 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 Right Heart Ejection Fraction Oximetry catheter
Indications For Use:
Models: D754F75 and 759F75
The REF/Ox catheters (Models D754F75 and 759F75) are indicated for continuous mixed venous oxygen saturation in addition to the prior listed indications. For Models D754F75 and 759F75, 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.

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.

SECTION 5 – 510(k) SUMMARY

Swan-Ganz catheters 510(k)	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Mugdha Dongre Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250-5167
Date Prepared	January 13th, 2016
Trade Name	Swan-Ganz catheters
Common Name	Cardiovascular Diagnostic Catheters
Classification Name	DYG – Catheter, flow directed DQE – Catheter, Oximeter, Fiberoptic DQO – Catheter, Intravascular, Diagnostic KRA – Catheter continuous flush
Regulation Class/Product Code	DYG-870.1240 DQE-870.1230 DQO-870.1200 KRA-870.1210
Predicate Device(s)	K001063, K810124, K810352, K820222, K894168, K905458, K910204, K924661, K934742, K951566
Device Description	The Swan-Ganz catheters are well known pulmonary artery catheters intended for use on critical care patients. A Swan-Ganz Catheter includes an inflatable balloon at the tip, which facilitates its placement into the pulmonary artery through the flow of blood. The catheters can be grouped together based on functionality. The Swan-Ganz catheters can be used with compatible cardiac output patient monitors and/or with oximetry modules (depending on the model number) to transmit signals for hemodynamic pressure monitoring, cardiac output measurements, and/or oximetry measurements. The Swan-Ganz catheters are to be used with the Edwards and/or Edwards' compatible patient monitors, such as the Vigilance II.
Models	**Base Catheters:** 111F7, 111F7P, S111F7, 123F6, 123F6P, T123F6, 110F5, 116F4, 115F7, 115F7P, 114F7, 114F7P, 131F7, 131F7P, 131VF7P 141F7, 143TF7, 151F7, 831F75, 831F75P, 831VF75P, 834F75, 096F6, 096F6P, TS105F5 132F5, 931F75, 991F8, C144F7, S144F7, C145F6N C146F7, S9FC146F7, T173F6 **Advanced Catheters:** 139F75, 744F75, 746F8, 177F75N, 774F75, 777F8, 757F8, 631F55N, 780F75M, 782F75M, D754F75, 759F75
Device Characteristics	Single Use, Sterile (EtO)

Indications for Use/ Intended Use	**Swan-Ganz catheters** **Device Name:** Swan-Ganz Flow-Directed Monitoring catheters Double and Triple Lumen **Indications For Use:** **Models: 111F7, 111F7P, S111F7, T111F7, 123F6, 123F6P, T123F6, 110F5, 116F4, 115F7, 115F7P, 114F7 and 114F7P** 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, VIP and VIP+, True Size **Indications For Use:** **Models: 131F7, 131F7P, 131VF7P, 141F7, 143TF7, 151F7, 831F75, 831F75P, 831VF75P, 834F75, 096F6, 096F6P, TS105F5 and 132F5** 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- Thermodilution Paceport catheters, Thermodilution A-V Paceport catheters **Indications For Use:** **Model 931F75** The Swan-Ganz thermodilution Paceport catheters (Model 931F75) are used for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The Paceport catheter (Model 931F75) may also be used for standby temporary ventricular pacing. 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. **Model 991F8** The Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) is indicated for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions. The A-V Paceport catheter (Model 991F8) is also indicated for standby temporary ventricular, atrial, or A-V sequential pacing using the Model D98100 Chandler Transluminal V-pacing probe and/or Model D98500 A-pacing probe. 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, Synthetic ControlCath Thermodilution Catheters, Polymer Blend True Size Torque Support Thermodilution catheter **Indications For Use:** **Models: C144F7, S144F7, C145F6N, C146F7 and S9FC146F7** ControlCath 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. **Model: T173F6** 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 Continuous Cardiac Output Thermodilution catheters - CCO Catheters, CCO/SvO_2 Catheters, CCO/ SvO2/ VIP Catheters, CCO V CCO/ CEDV Catheters, CCOmbo V CCO/SvO2/CEDV Catheters, CCOmbo V CCO/SvO2/ CEDV/VIP Catheters **Indications For Use:** **Models: 139F75, 744F75, 746F8, 177F75N, 774F75 and 777F8** The primary indications for the Swan-Ganz CCO thermodilution catheters include: • 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 Models with CEDV capabilities are also indicated for volumetric determinations Secondary indications include the following: • Blood Sampling • Infusion of saline and dextrose solutions **Device Name:** Swan-Ganz Continuous Cardiac Output/End Diastolic Volume Thermodilution catheter, CCOmbo EDV CCO/SvO2/EDV/VIP **Indications For Use:** **Model: 757F8** The primary indications for the CCOmbo EDV TD catheters include: • Acute heart failure • Severe hypovolemia • Complex circulatory situations • Medical emergencies • Adult respiratory distress syndrome • Gram negative sepsis • Multi system organ failure • 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 • Volumetric 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

	Device Name: Swan-Ganz Oximetry TD catheter- Oximetry catheters, Oximetry Paceport catheter, VIP Oximetry catheter **Indications For Use:** **Models: 631F55N, 780F75M and 782F75M** 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. The oximetry Paceport catheters (model 780F75M) are also indicated for standby temporary ventricular pacing using the model D98100 Chandler transluminal V-pacing probe. For all models, 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 Right Heart Ejection Fraction Oximetry catheter **Indications For Use:** **Models: D754F75 and 759F75** The REF/Ox catheters (Models D754F75 and 759F75) are indicated for continuous mixed venous oxygen saturation in addition to the prior listed indications. For Models D754F75 and 759F75, 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.
Environment of Use	Healthcare facility/hospital
Materials of Use	Polyvinyl Chloride, Pellethane, Tanatlum, Nylon, Stainless Steel, Latex or Synthetic material.
Key Performance Specifications	The proposed contraindication change and the MR Safe claim do not have any effect on the design, materials, technology and operating principles of current legally marketed device. Therefore no additional performance testing was required.
Comparative Analysis	The scientific technology and materials of the subject device are unchanged from the legally marketed predicate device. The proposed MR safe claim (Models: 111F7, 111F7P, S111F7, T111F7, 123F6, 123F6P, T123F6, 110F5, 116F4, 115F7, 115F7P, 114F7, 114F7P) has been evaluated and was confirmed to be MR Safe. Additional contraindications were added to IFUs to maintain consistency across the product family.
Functional/ Safety Testing	Swan-Ganz Flow Directed Monitoring catheter was evaluated for MRI compatibility and was confirmed to be MR Safe.

Comparision of Technology to Predicate Devices	Performace evaluation was conducted to compare the proposed device(s) to the predicate devices(s). The result of the performance evaluation indicates that the scientific technology and material of the proposed devices are unchanged from the legally marketed device(s) (predicate). The change made to the proposed device is a modification of the MRI status to MR Safe. There are no changes to the design, materials or manufacturing process.
Conclusion	Swan-Ganz catheters have been shown to be safe, effective, and substantially equivalent to the respective predicate devices (Swan-Ganz catheters) for their intended use in hospitals and other appropriate clinical environments.