June 27, 2024

Edwards Lifesciences
Anna Hwang
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K233983
Trade/Device Name: Swan-Ganz Pacing Probe and Catheters; Swan-Ganz Bipolar Pacing Catheter (D97120F5); Swan-Ganz Bipolar Pacing Catheter (D97130F5); Swan-Ganz Pacing Thermodilution TD Catheter (D200F7); Chandler Transluminal V-Pacing Probe (D98100)
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-directed catheter
Regulatory Class: Class II
Product Code: DYG, LDF
Dated: May 24, 2024
Received: May 28, 2024

Dear Anna Hwang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara M. Royce -S

Digitally signed by Sara M. Royce -S
Date: 2024.06.27 14:46:29 -04'00'

Sara Royce
Assistant Director
DHT2A: Division of Cardiac

Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K233983

Device Name

Swan-Ganz Pacing Probe and Catheters;
Swan-Ganz Bipolar Pacing Catheter (D97120F5);
Swan-Ganz Bipolar Pacing Catheter (D97130F5);
Swan-Ganz Pacing Thermodilution TD Catheter (D200F7);
Chandler Transluminal V-Pacing Probe (D98100)

Indications for Use *(Describe)*

The Swan-Ganz pacing-TD catheters are indicated for use for temporary, atrial, ventricular, or A-V sequential cardiac pacing of adult surgical and/or critically ill patients. This includes, but is not limited to, patients with arrythmias, acute myocardial infarction, cardiac surgery, and coronary angiography. In addition, these catheters are indicated for use in hemodynamic monitoring of patients experiencing medical conditions such as, but not limited to, post-major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, stroke, and cardiac disease including heart failure.

The Swan-Ganz bipolar pacing catheters are indicated for use in surgical and/or critically ill cardiac patients who may benefit from temporary, transvenous right ventricular pacing.

The Chandler transluminal V-pacing probe is a transluminal bipolar pacing probe, which must be used with a Swan-Ganz Paceport catheter is indicated for use in adult surgical and/or critically ill cardiac patients. This includes, but is not limited to, patients with arrhythmias, acute myocardial infarction, cardiac surgery and coronary angiography.

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.

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**510(k) SUMMARY**

| Swan-Ganz Pacing Probe and Catheters | | |
|---|---|---|
| **510(k) Submitter** | Edwards Lifesciences LLC<br>One Edwards Way<br>Irvine, CA 92614<br>(949) 250-111 | |
| **Contact Person** | Anna Hwang<br>Manager, Regulatory Affairs<br>Edwards Lifesciences<br>One Edwards Way<br>Irvine, CA 92614<br>Telephone: (949) 250 - 0902<br>Fax: (949) 809 - 7303<br>Email:<br>Anna_Hwang@edwards.com | Karen O'Leary<br>Sr. Director, Regulatory Affairs<br>Edwards Lifesciences<br>One Edwards Way<br>Irvine, CA 92614<br>Telephone: (949) 610-9179<br>Fax: (949) 809 - 7214<br>Email:<br>Karen_Oleary@edwards.com |
| **Date Prepared** | December 15, 2023 | |
| **Trade Name** | Swan-Ganz Pacing probe and catheters | |
| **Regulation Number/ Regulation Name** | 21 CFR §870.1240<br>21 CFR §870.3680 | |
| **Product Code** | DYG - Flow-directed catheter<br>LDF - Cardiovascular permanent or temporary pacemaker electrode | |
| **Regulation Class** | Class II | |
| **Predicate Device** | Swan-Ganz Flow Directed Catheter<br>(K791183, cleared on July 12, 1979)<br><br>Swan-Ganz Bipolar Pacing Catheter<br>(K822723, cleared on Oct 15, 1982)<br><br>Chandler Transluminal Bipolar Pacing Probe<br>(K152633, cleared Oct 15, 2015) | |
| **Device Description** | The Swan-Ganz Pacing Catheters and Pacing Probes are a series of specialized catheters and pacing probes, which are temporarily inserted into the central circulatory system vasculature to facilitate temporary atrial, ventricular, or A-V sequential pacing and to serve as diagnostic and/or therapeutic tools. The catheters may be used to overdrive suppression of arrhythmias and diagnosis of complex arrhythmias. The pacing catheters and probes may be used for ECG detection during placement but are not intended to be used for ECG monitoring. | |

| Swan-Ganz Pacing Probe and Catheters | |
|---|---|
| **Indications for Use** | The Swan-Ganz pacing-TD catheters are indicated for use for temporary, atrial, ventricular, or A-V sequential cardiac pacing of adult surgical and/or critically ill patients. This includes, but is not limited to, patients with arrythmias, acute myocardial infarction, cardiac surgery, and coronary angiography. In addition, these catheters are indicated for use in hemodynamic monitoring of patients experiencing medical conditions such as, but not limited to, post-major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, stroke, and cardiac disease including heart failure.<br><br>The Swan-Ganz bipolar pacing catheters are indicated for use in surgical and/or critically ill cardiac patients who may benefit from temporary, transvenous right ventricular pacing.<br><br>The Chandler transluminal V-pacing probe is a transluminal bipolar pacing probe, which must be used with a Swan-Ganz Paceport catheter is indicated for use in adult surgical and/or critically ill cardiac patients. This includes, but is not limited to, patients with arrhythmias, acute myocardial infarction, cardiac surgery and coronary angiography. |
| **Comparative Analysis** | The subject device is identical to the predicate device in terms of the technological characteristics including design, material, chemical composition, and principle of operation.<br><br>The subject devices indications for use were updated for clarification purposes, with inclusion of medical and clinical conditions of use, while also removing redundancy. The indications for use and changes to the labeling were updated in compliance with the European Union Medical Device Regulations (EU MDR), and in better alignment with 21 CFR 841.20 requirements. |
| **Device Testing** | Biocompatibility testing was performed in accordance with ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and 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", issued on September 4, 2020.<br><br>Bench testing was performed in accordance with Edwards' design requirements. In addition, shelf-life, packaging, and sterilization validations have been performed.<br><br>All testing met the existing predetermined acceptance criteria |
| **Conclusion** | The Swan-Ganz Pacing probe and catheters remain substantially equivalent to the predicate devices. |