June 6, 2024

Edwards Lifesciences LLC
Bedalin Lugo Rodriguez
Regulatory Affairs Manager
One Edwards Way
Irvine, California 92614

Re: K233824
Trade/Device Name: Swan-Ganz catheter
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-Directed Catheter
Regulatory Class: Class II
Product Code: DYG, DQE, DQO, KRA
Dated: November 30, 2023
Received: December 1, 2023

Dear Bedalin Lugo Rodriguez:

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,

Robert T. Kazmierski -S

for

LCDR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233824

Device Name

Swan-Ganz catheter

Indications for Use *(Describe)*

The Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

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.

510(k) SUMMARY

Swan-Ganz Base and Advanced catheters		
510(k) Submitter	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 (949) 250-111	
Contact Person	Bedalin Lugo Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (787) 229-5433 Fax: (949) 809 - 2954 Email: Bedalin_lugo@edwards.com	Aditi Iyengar Sr. Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250-3478 Fax: (949) 809 - 2954 Email: Aditi_Iyengar@edwards.com
Date Prepared	November 30, 2023	
Trade Name	Swan-Ganz catheters	
Regulation Number/ Regulation Name	21 CFR §870.1240 - Catheter, Flow Directed 21 CFR §-870.1230 - Catheter, Oximeter, Fiberoptic 21 CFR §870.1200 - Catheter, Intravascular, Diagnostic 21 CFR §870.1210 – Catheter, Continuous Flush	
Product Code	DYG, DQE, DQO and KRA	
Regulation Class	Class II	
Predicate Device	K160084, K222117	
Reference Device	K231248	
Device Description	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.	
Indications for Use	Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.	

Swan-Ganz Base and Advanced catheters	
Comparative Analysis	The subject Swan-Ganz Base and Advanced catheters are identical to the predicate devices cleared in K160084 and K222117 in terms of design, performance specifications, and technological characteristics with the exception of the indications for use statement and other portions of the labeling. The are no changes to the design, technology, performance, materials, or specifications of the devices in this 510(k). The modifications to the subject devices are limited to labeling changes. The indications for use and labeling differences were updated to be in compliance with the European Union Medical Device Regulations (EU MDR), ISO 20147:2021, ISO 15223-1:2021, and in better alignment with 21 CFR 841.20 requirements. These labeling changes provide additional clarifying details and did not raise any new concerns of safety and effectiveness or introduce any new clinical uses for the subject devices.
Conclusion	The Swan-Ganz catheters remain safe, effective, and substantially equivalent to the predicate devices.