September 17, 2025

Edwards Lifesciences LLC
Abby Geater
Senior Specialist Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K251688
Trade/Device Name: Carpentier-Edwards Physio Annuloplasty Ring (4450)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: May 27, 2025
Received: June 2, 2025

Dear Abby Geater:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Samuel G. Raben -S

Samuel Raben, PhD
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251688

Device Name
Carpentier-Edwards Physio Annuloplasty Ring, model 4450

Indications for Use *(Describe)*
The Carpentier-Edwards Physio annuloplasty ring is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve.

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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Edwards

510(k) Summary

Submitter: **Contact Person:**	Edwards Lifesciences LLC Abby Geater, Senior Specialist, Regulatory Affairs One Edwards Way Irvine, CA 92614 (949) 250-3179
Date Prepared:	May 27, 2025
Trade Name:	Carpentier-Edwards Physio Annuloplasty Ring, model 4450
Classification Name:	Annuloplasty Ring 21 CFR Part 870.3800, Product Code KRH, Class II (Special Controls)
Predicate Device:	K926138 Carpentier-Edwards Physio Annuloplasty Ring, model 4450
Device Description:	The Carpentier-Edwards Physio annuloplasty ring, Model 4450 is constructed of Elgiloy* bands separated by polyester film strips and has a sewing ring margin that consists of a layer of silicone rubber covered with a woven polyester cloth. The mitral annuloplasty ring conforms to the configuration of a normal mitral annulus. It is kidney-shaped with one long curved segment corresponding to the posterior leaflet annulus. A rectilinear portion corresponds to the anterior leaflet annulus. Transverse colored threads indicate the anterior and posterior commissures. The ring exhibits characteristics of differential flexibility. While retaining stiffness, the annuloplasty ring is also flexible in the portion corresponding to the anterior leaflet. The flexibility is increased in the posterior regions of the ring. Along the annular plane the ring is

	stable with a saddle-shaped curve for apposition to the aortic root. The design is intended to provide support after annuloplasty surgery. The ring maintains a fixed maximum annular dimension to prevent excessive distension of the natural valve annulus while adapting to the dynamic motion of the mitral annulus throughout the cardiac cycle. The holder, designed to facilitate ring implantation, is manufactured from an amorphous polymer. The annuloplasty ring is mounted on the holder with three retaining sutures. The handle, Model 1150, may be utilized in conjunction with the holder to facilitate ease of suture placement and implantation. The middle section of the handle is malleable, allowing the handle to be adjusted (bent) in a configuration convenient for use. The handle is packaged separately. The snap assembly of the handle and holder allows for connecting and disconnecting the two components at appropriate times during the surgical procedure.
Indications For Use:	The Carpentier-Edwards Physio annuloplasty ring is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve. A comparison of the characteristics of the proposed device and the predicate devices shows the Carpentier-Edwards Physio Annuloplasty Ring to have the same fundamental technological characteristics as the predicate device that has received 510(k) clearance.
Comparative Analysis:	Equivalence is based upon intended use, indications for use, principles of operation, and fundamental scientific technology. Both devices are intended to repair a malfunctioning heart valve.

	Both rings have identical structure, materials of composition, sterilization method, size range, sizing accessories, packaging, and site of application in the body. To verify that device design meets safety and performance requirements, representative samples of the devices underwent MRI testing in accordance with applicable standards and guidance. These data provide an acceptable assurance of the safety and effectiveness of the Carpentier-Edwards Physio Annuloplasty Ring.
Functional/Safety Testing:	Performance testing was performed: • MRI Compatibility
Conclusion:	The Carpentier-Edwards Physio Annuloplasty Ring is substantially equivalent to the named predicated device based on technological comparison, principle of operation, indications for use, and intended use. MRI testing was done to ensure safety and effectiveness of the device as compared to the predicate.