December 16, 2019

Edwards Lifesciences LLC
Milinda Mawley
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K192762
Trade/Device Name: Physio Flex Annuloplasty Ring, model 5300
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: October 17, 2019
Received: October 18, 2019

Dear Ms. Mawley:

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,

for Nicole G. Ibrahim, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192762

Device Name
PHYSIO FLEX Annuloplasty Ring, Model 5300

Indications for Use *(Describe)*
The Physio Flex Annuloplasty Ring, model 5300, is indicated for the correction of mitral valve insufficiency, or mixed mitral insufficiency, where treatment does not necessitate 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.

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510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person*:*	Milinda Mawley, Senior Specialist, Regulatory Affairs One Edwards Way Irvine, CA 92614 (949) 250-5847
Date Prepared:	September 27, 2019
Trade Name:	PHYSIO FLEX Annuloplasty Ring, model 5300
Classification Name*:*	Annuloplasty ring 21 CFR Part 870.3800, Product Code KRH, Class II (Special Controls)
Predicate Device:	K083470 Carpentier-Edwards Physio II annuloplasty ring, model 5200
Device Description:	The Physio Flex annuloplasty ring is a semi-rigid, open, mitral annuloplasty ring with an asymmetrical open anterior segment. The ring has an asymmetrical open anterior segment corresponding to the mitral annulus below the aorto-mitral curtain. The complete portion of the ring begins at the anterolateral commissure and extends beyond the posteromedial commissure and the posteromedial trigone into the anterior annulus. The ring design has a rectangular Nitinol core which enables different flexibilities in-plane and out-of-plane. The ring flexibility progressively increases in-plane from size 24 mm to 30 mm. It remains relatively constant from size 30 mm to 40 mm. For each ring size, the out-of-plane flexibility is greater than the in-plane flexibility. The ring also has a progressive saddle height with a complete posterior saddle and an open anterior saddle. The ratio of the saddle height to the A-P (antero-lateral to postero-medial) dimension progressively increases from size 24 mm to size 36 mm. It remains constant from size 36 mm to 40 mm. The Nitinol core is covered with a silicone sleeve and an external, knitted, polyester cloth. The sewing cuff is designed for ease of needle penetration and suture placement. A green circumferential suture line placed between the outer perimeter of the ring and the outer perimeter of the Nitinol core identifies the suture placement area. The ring has two commissure markers and a mid-posterior marker to facilitate orientation during implantation.

	The ring incorporates a holder with a proximal arm for connection to handle models 1150 and 1151. The holder arm is designed with a section made of stainless steel that can be bent to facilitate access and positioning of the ring on the valve annulus. The Physio Flex annuloplasty ring is available in sizes 24, 26, 28, 30, 32, 34, 36, 38 and 40 mm. The Physio Flex annuloplasty ring is designed to be used with sizer model 1252.
Indications For Use:	The Physio Flex Annuloplasty Ring, model 5300, is indicated for the correction of mitral valve insufficiency, or mixed mitral insufficiency, where treatment does not necessitate replacement of the natural mitral valve.
Comparative Analysis:	A comparison of the characteristics of the proposed device and the predicate devices shows the Physio Flex Annuloplasty Ring to have the same fundamental technological characteristics as the predicate device that has received 510(k) clearance. 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 similar or identical structure, materials of composition, sterilization method, size range, sizing accessories, packaging, and site of application in the body. The subject device differs from the predicate in its open design and core material.
Functional/Safety Testing:	To verify that device design meets functional and performance requirements, representative samples of the devices underwent testing in accordance with applicable standards and guidance. These data demonstrate the device is substantially equivalent to the predicate. Performance testing was performed to support substantial equivalence, including: • Ring parachuting • Holder removal • Fatigue Life Analysis • Magnetic Resonance • Corrosion Resistance • Biocompatibility
Conclusion:	The Physio Flex Annuloplasty Ring is substantially equivalent to the named predicate device based on technological comparison, principle of operation, indications for use, and intended use. There are no new questions of safety and effectiveness.