DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 26, 2017

Edwards Lifesciences LLC
Lisa Hessabi
Associate Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K163693
Trade/Device Name: IntraClude Intra-Aortic Occlusion Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 22, 2016
Received: December 28, 2016

Dear Lisa Hessabi:

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,

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)*

K163693

Device Name
IntraClude™ Intra-Aortic Occlusion Device

Indications for Use *(Describe)*

The IntraClude™ Intra-Aortic Occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

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

Submitter:	Edwards Lifesciences LLC
Contact Person*:*	Lisa G. Hessabi, Associate Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 (949) 250-5000
Date Prepared:	January 25, 2017
Trade Name:	IntraClude™ Intra-Aortic Occlusion Device
Classification Name*:*	Vascular Clamp 21 CFR Part 870.4450, Product Code DXC, Class II
Predicate Device:	K132175 IntraClude™ Intra-Aortic Occlusion Device
Device Description:	The IntraClude Intra-Aortic Occlusion Device (model code ICF100) is a 10.5 Fr (3.5mm), triple-lumen, 100-cm-long catheter with an elastomeric balloon near its distal tip designed to occlude the ascending aorta in order to partition the aortic root from arterial circulation during cardiopulmonary bypass (CPB). The balloon expands to occlude a range of aorta sizes from 20 to 40 mm. The shaft is provided with an extended strain relief, which tapers from 10.5 Fr to the remaining 9 Fr catheter, and is designed to prevent kinking and to avoid compressing the shaft when the hemostasis valve of an arterial cannula introducer sheath is firmly closed around the catheter body. The large central lumen of the IntraClude device serves three functions: accommodating the guidewire, delivering cardioplegia solution to the aortic root, and venting fluid and air from the aortic root. The two remaining lumens serve as conduits for balloon inflation/deflation and aortic root pressure monitoring. The hub has two flexible extension tubes with an integrated luer connection to provide access for accessories. The shaft is provided with markers to

	indicate the insertion depth. A Clamp-Lock™ device, provided on the extended strain relief portion, allows the IntraClude device to be locked in position to prevent balloon migration during aortic occlusion. The devices are provided sterile and non-pyrogenic; they are intended for single use only.
Indications For Use:	The IntraClude™ Intra-Aortic Occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.
Comparative Analysis:	Testing demonstrates that the IntraClude device is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The subject device differs from the predicate because of modifications to the strain relief, the addition of a 22 mm sleeve at the hub-to-strain-relief transition, and the change in pad printing inks. The IntraClude device was fully assessed within the Edwards' Risk Management and Design Controls systems.
Functional/Safety Testing:	The following functional tests were performed: • Biocompatibility – Per ISO 10993-1:2009/ Cor 1: for External communicating device, direct circulating blood path, duration ≤ 24 hours: tests included Cytotoxicity, Hemolysis, Systemic Toxicity, Irritation, and Sensitization. • Tensile and Compression/friction testing – Confirmation of the strength of the catheter, lumens, and clamp lock. • Flow Rate – Inspection of catheter, lumens, and accessories for cardioplegia flow rate and pressure drop.

	• Catheter Bending/Kink Testing – Inspection of catheter, lumens, and accessories to confirm functionality after manipulation of the catheter. • Leakage Testing – Confirmation of device integrity after exposure to pressurized air and manipulation of the catheter, lumens, and accessories. All data met pre-determined acceptance criteria. Design Validation was performed by clinicians using a simulated use model to verify that the modifications to the IntraClude device meet the user requirements and intended use.
Conclusion:	The IntraClude Intra-Aortic Occlusion Device is substantially equivalent to the cited predicate device.