510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Luke Meidell, Regulatory Affairs Associate II 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6212
Date Prepared:	September 12, 2013
Trade Name:	Edwards Lifesciences® IntraClude™ Intra-Aortic Occlusion Device
Classification Name:	Vascular Clamp 21 CFR Part 870.4450, Product Code DXC, Class II
Predicate Device:	K113182: IntraClude™ Intra-Aortic Occlusion Device

SEP 13 2013

Device Description:

The IntraClude Intra-Aortic Occlusion Device is a 10.5 Fr (3.5 mm), 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. This device is designed to be used in the femoral approach with the Edwards arterial cannula/introducer sheath.

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 catheter 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 blue Clamp-Lock device, provided on the extended strain relief portion, allows the IntraClude catheter to be locked in position to prevent balloon migration during aortic occlusion. For situations

where the 9 Fr section of the device is outside of the arterial cannula or introducer sheath, a white suture loop/box clamp is provided for locking the catheter in position.

The IntraClude catheter is packaged sterile and non-pyrogenic and is for single use only.

Indications For Use:
The IntraClude Intra-Aortic Occlusion Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion Catheter 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:
The subject device has the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate device. It has been demonstrated that the subject IntraClude device is comparable to the predicate device in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised as a result of the design modifications.

Functional/Safety Testing:
The following functional and accelerated aging bench testing was performed. All data met acceptance criteria.

- Biocompatibility – cytotoxicity and pyrogenicity – Per ISO 10993-1 for External communicating device, direct circulating blood path, duration ≤ 24 hours.
- Tensile testing – device hub to shaft – Confirmation of the bond strength of the catheter, lumens, and connected accessories.
- Kink testing – axial kink force, kink test under tension, hub kink test – Confirmation of kink resistance of the catheter, lumens, and connected accessories.
- Dimensional testing – Analysis of shaft outer diameter, distal curve, and marking distance.
- Clamp lock testing – Confirmation that the clamp lock functions with the catheter shaft.
- Design Validation – Design was validated through bench top in-vitro studies.

Conclusion:
The IntraClude Intra-Aortic Occlusion Device is substantially equivalent to the cited predicate device. Additionally, the IntraClude device met all acceptance criteria to confirm safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Edwards Lifesciences, LLC
Mr. Luke Meidell
Regulatory Affairs Associate II
12050 Lone Peak Pkwy
Draper, UT 84020

Re: K132175
Trade/Device Name: Edwards Lifesciences ® IntraClude™ Intra-Aortic Occlusion Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: July 12, 2013
Received: July 15, 2013

Dear Mr. Meidell:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

M A Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K132175

Device Name: Edwards Lifesciences IntraClude Intra-Aortic Occlusion Catheter

The IntraClude Intra-Aortic Occlusion Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion Catheter 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.

Prescription Use x OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)