K113411

JUN 11 2012

510(k) Summary

Submitter:	Edwards Lifesciences® LLC
Contact Person:	Dannette Crooms, Senior Regulatory Affairs Associate 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6209
Date Prepared:	November 17, 2011
Trade Name:	Edwards Lifesciences® Vent Catheters
Classification Name:	cardiopulmonary bypass vascular catheter, cannula or tubing Class II (21 CFR §870.4210).
Predicate Device:	K831769 – Various Cardiovascular Surgical Devices - Vent Catheters

Device Description:

Edwards Lifesciences atrial and left ventricular vent catheters consist of soft tubing with a radiused tip attached to a rigid clear plastic rear hub. Each catheter has a perforated venting segment and depth marker rings. Through the center of each catheter, extending slightly beyond the catheter tip and attached to the rear hub by a plastic locking device, is a removable rigid plastic stylet to facilitate insertion of the catheter. Silicone catheters have a closed tip and a malleable stainless steel stylet with a non-locking hub. Models intended for right atrial insertion have additional side holes. Edwards Vent Catheters are also available with Duraflo® coating.

Intended Use:

Venting the left heart during Cardiopulmonary Bypass (CPB).

Indications for Use:

Atrial Vent Catheters are intended for venting the left heart during short–term (≤6 hrs) cardiopulmonary bypass. Avoid direct ventriculotomy with entry into the left atrium across the mitral valve and into the left ventricle.

Left Ventricular Vent Catheters are intended for venting the left ventricle during short–term (≤6 hrs) cardiopulmonary bypass. Entrance is made into the left ventricle.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Vent Catheters may be used in pediatric or adult populations based on individual patient anatomy.

Comparative Analysis:

The basis for this submission is a clarification of the Indications for Use statement. No physical changes are being made to these devices. The subject devices have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. It has been demonstrated that the subject Vent Catheters are comparable to the predicate devices in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised.

Functional/Safety Testing:

No functional testing was performed in support of the change to the Indications for Use.

Conclusion:

The Vent Catheters are substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 1 1 2012

Edwards Lifesciences, LLC
c/o Mr. Dannette Crooms
Sr. Regulatory Affairs Associate
12050 Lone Peak Parkway
Draper, UT 84020

Re: K113411
Edwards Atrial and Left Ventricular Vent Catheters Model numbers E060, 061, E063, SPC2131, ISP3013, DIIE061, PE062, and EM012
Regulation Number: 21 CFR 870.4210
Regulation Name: Vascular Catheter, Cannula or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: March 7, 2012
Received: March 8, 2012

Dear Mr. Crooms:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

510(k) Number (if known): K113411

Device Name: Edwards Lifesciences Vent Catheter

Indications for Use:

Atrial Vent Catheters are intended for venting the left heart during short-term (≤6 hrs) cardiopulmonary bypass. Avoid direct ventriculotomy with entry into the left atrium across the mitral valve and into the left ventricle.

Left Ventricular Vent Catheters are intended for venting the left ventricle during short-term (≤6 hrs) cardiopulmonary bypass. Entrance is made into the left ventricle.

Extracorporeal circuit components with a Duraflo® coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Vent Catheters may be used in pediatric or adult populations based on individual patient anatomy.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113411