510(k) Summary

JUL 0 3 2014

Submitter:	Edwards Lifesciences, LLC One Edwards Way Irvine, CA 92614
Contact:	Eric Carrier, Phone: 949-250-6443, Fax: 949-809-5655
Prepared:	January 28, 2014
Trade Name:	Balloon Catheter
Common Name:	Percutaneous Catheter
Classification:	Catheter Introducer 21 CFR 870.1250, Product Code OZT
Predicate Device(s):	Loma Vista Medical (BARD) TRUE Dilation Balloon Valvuloplasty Catheter (K121083), and the Z-MED and Z-MED II™ Balloon Aortic Valvuloplasty & Percutaneous Transluminal Valvuloplasty Catheter (K122012).

Device Description:

The Edwards Balloon Catheter, is used for balloon aortic valvuloplasty. The device consists of a nylon balloon, a thermoplastic elastomer (Polyether block amide) multidurometer braided shaft with 130cm working length, platinum/iridium radio-detectable markers, and a polycarbonate y-connector that consists of a balloon inflation port and guidewire lumen. The effective length of the balloon is 4cm and is offered in 16mm, 20mm, 23mm and 25mm diameters. The balloon catheter is supplied sterilized by ethylene oxide for single use.

Indication:

The Edwards Balloon Catheter is indicated for balloon aortic valvuloplasty.

Comparison to Predicate:

The Edwards Balloon Catheter is substantially equivalent to Loma Vista Medical (BARD) TRUE Dilation Catheter, 510(k) No.: K121083 and the Z-MED and Z-MED II™ Balloon Aortic Valvuloplasty & Percutaneous Transluminal Valvuloplasty Catheter, 510(k) No.: K122012.

Summary of Non-Clinical Testing:

Non-clinical testing was completed to demonstrate that the Edwards Balloon Catheter met the established performance characteristics , and to verify that design requirements are satisfied. Testing included biocompatibility evaluation per ISO 10993-1, ethylene oxide sterilization validation, and package qualification. Device functional testing included, Surface/Visual Inspection, Dimensional Inspection: Catheter and Balloon Working Length, Balloon

Inflation/Deflation Time, Balloon Maximum Inflation Pressure for Nominal Volume, Balloon Diameter at Nominal Volume, Balloon Catheter Retrieval Force, Balloon Fatigue and Burst, Marker Band Bond Verification, Bond Strength: Catheter Shaft/Hub, and Bond Strength: Catheter Shaft/Hub (Torque).

Summary of Clinical Data:

Clinical assessment for the Edwards Transfemoral Balloon Catheters consisted of a literature review, complaint analyses for the Edwards Transfemoral Balloon Catheter and RetroFlex Balloon Catheter, and review of post-market experience with the Edwards Transfemoral Balloon Catheter. This data, in combination with the results of the pivotal IDE G030069 (with the RetroFlex Balloon Catheter) reviewed as part of PMA P100041, provides reasonable assurance that the Edwards Transfemoral Balloon Catheter is safe and effective for its indicated use.

Conclusion:

The Edwards Catheter is substantially equivalent to the predicate devices (Loma Vista Medical (BARD) TRUE Dilation Catheter the Z-MED and Z-MED II™ Balloon Aortic Valvuloplasty & Percutaneous Transluminal Valvuloplasty Catheter.

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

March 20, 2015

Edwards Lifesciences, LLC.
Eric Carrier
Sr. Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K140241
Trade/Device Name: Edwards Balloon Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: June 4, 2014
Received: June 5, 2014

Dear Mr. Carrier:

This letter corrects our substantially equivalent letter of July 3, 2014.

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" (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 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 yours,

Nicole G. Ibrahim -S

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

Enclosure

K140241

Indications For Use Statement

510(k) Number (if known)	
Device Name	Edwards Balloon Catheter
Indications for Use	The Edwards Balloon Catheter is indicated for balloon aortic valvuloplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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