



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 07, 2016

Edwards Lifesciences LLC
Mr. Chris Kennelly
Regulatory Affairs Associate II
One Edwards Way
Irvine, California 92614

Re: K153069
Trade/Device Name: Edwards Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: OMZ
Dated: October 21, 2015
Received: October 22, 2015

Dear Mr. Kennelly:

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 yours,



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

Enclosure

Indications for Use

510(k) Number (if known)

K153069

Device Name

Edwards Balloon Catheter

Indications for Use (Describe)

The Edwards Balloon Catheter is indicated for balloon pulmonic valvuloplasty.

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
(K153069)

Submitter: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

Contact: Chris Kennelly
Phone: 949-250-2019
Fax: 949-809-5655

Prepared: October 20, 2015

Trade Name: Edwards Balloon Catheter

Common Name: Balloon valvuloplasty catheter

Classification: Pulmonary (Pulmonic) Valvuloplasty Catheter, 21 CFR 870.1250
Product Code: OMZ

Predicate Device: NuMed Z-MED™ Balloon Dilatation Catheter (K040830)

Device Description:

The Edwards Balloon Catheter is used for balloon pulmonic valvuloplasty. The device consists of a nylon balloon, a thermoplastic elastomer (polyether block amide) multi-durometer braided shaft with 130 cm 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 4 cm and is offered in 16 mm, 20 mm, 23 mm and 25 mm diameters.

Indications for Use:

The Edwards Balloon Catheter is indicated for balloon pulmonic valvuloplasty.

Comparison to Predicate:

The Edwards Balloon Catheter is substantially equivalent to the predicate device in intended use, design, technology and performance. The Edwards Balloon Catheter differs from the predicate device in introducer size compatibility, rated burst pressure, catheter length, material composition and inflation method. The differences between the subject and predicate devices do not have an adverse impact on safety or effectiveness, as demonstrated by bench testing.

Summary of Non-Clinical Testing:

Non-clinical testing was completed to demonstrate that the Edwards Balloon Catheter meets 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, radiopacity, balloon diameter, insertion force into sheath, balloon inflation/deflation time, balloon compliance, catheter kink test, balloon catheter retrieval force, balloon fatigue and burst, leakage test, and bond testing.

Conclusion:

The Edwards Balloon Catheter is substantially equivalent to the predicate device, the NuMed Z-MED™ Balloon Dilatation Catheter.