K110103 p 1/2

510(k) Summary

Submitter:	Edwards Lifesciences® LLC
Contact Person:	Spencer Walker, Regulatory Affairs Associate II 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6100
Date Prepared:	January 11, 2011
Trade Name:	Edwards Lifesciences® Left Atrial Pressure Monitoring Catheter – (LAP)
Classification Name:	Catheter Intravascular Diagnostic 21 CFR Part 870.1200, Product Code DQO, Class II
Predicate Device:	K852197: Research Medical, Inc. LAP-CATH Left Atrial Pressure Monitoring Catheter

FEB 11 2011

Device Description:

The Edwards Lifesciences Left Atrial Pressure Monitoring Catheters consist of a radiopaque catheter bonded to a 3-way stopcock. Each catheter is marked at 1, 2, 3, and 4 centimeters for reference and is fitted over a pencil point stainless steel stylet. The proximal end of the stylet terminates in a male luer lock hub which is engaged by the proximal female port of the stopcock. Each catheter is provided with a moveable suture anchor. The devices are provided sterile, they are non-pyrogenic and they are intended for single use only.

Intended Use:

The Left Atrial Pressure Monitoring Catheters are intended to be used solely in conjunction with a standard hemodynamic pressure monitoring system to obtain continuous central vascular pressures via the left atrium during and/or after cardiac surgery.

Comparative Analysis:

It has been demonstrated that the Left Atrial Pressure Monitoring Catheter is comparable to the predicate device in intended use and other labeling, fundamental scientific technology, material types, principles of operation and functional performance evaluations. The stopcock material change has been fully assessed within the Edwards Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria. No new issues of safety or efficacy have been raised and the performance data demonstrate equivalence.

Functional/Safety Testing:

The functional data indicate that the Left Atrial Pressure Monitoring Catheter performs in a substantially equivalent manner when compared with the predicate device. The following functional tests were performed. All data met pre-established acceptance criteria.

- Biocompatibility – Per ISO 10993
- Hemocompatibility – Hemolysis Assay and clotting time coagulation assay.
- Stopcock Handle Rotation Torque - Tensile test of the stem/core and the stopcock housing.
- Stopcock Handle Leak Testing – Inspection for defects after exposure to dynamic water flow and manipulation of the stopcock stem/core.

K110103 p 2/2

- Stopcock Flow Redirection Testing – Inspection of proper liquid directional flow as indicated on stopcock lever.
- Stopcock Leakage – Testing for Pressure Decay within the stopcock stem/core.
- Stopcock Visual Inspection – Evaluated for component damage and discoloration.

Conclusion:

The Left Atrial Pressure Monitoring Catheter is substantially equivalent to the cited predicate device.

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

Edwards Lifesciences, LLC
C/O Mr. Spencer Walker, Regulatory Affairs Associate II
Cardiac Surgery Systems
12050 Lone Peak Pkwy
Draper, UT 84020

FEB 11 2011

Re: K110103
Trade/Device Name: Edwards Lifesciences Left Atrial Pressure Monitoring Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DQO
Dated: January 12, 2011
Received: January 13, 2011

Dear Mr. Walker:

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.

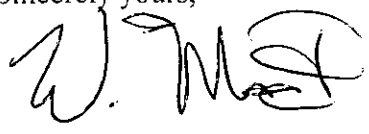
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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): K110103

Device Name: Edwards Lifesciences Left Atrial Pressure Monitoring Catheter

The Left Atrial Pressure Monitoring Catheters are intended to be used solely in conjunction with a standard hemodynamic pressure monitoring system to obtain continuous central vascular pressures via the left atrium during and/or after cardiac surgery.

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 K110103