K060660

APR 25 2006

510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Paula A. Torrianni, Director, Regulatory Affairs
Date Prepared:	October 28, 2005
Trade name:	EW200 System (Oxygen Saturation and Hemoglobin Monitoring System) PreSep Oximetry Catheter
Classification Name:	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) Catheter, Oximeter, Fiberoptic (21CFR870.1230)
Predicate Devices:	*Vigilance* Continuous Cardiac Output/Oximetry/Continuous End Diastolic Volume (CCO/SvO_2/CEDV) Monitor 3M CDI Blood Parameter Monitoring System 500 Central Venous Oximetry Probe Catheter and Probe Multi-Med Multi-Lumen Central Venous Catheter Edslab Dual Lumen Regional Saturation Oximetry Catheter
Device Description:	The EW200 System is a microprocessor-based instrument that, when connected to an Edwards oximetry catheter, provides continuous measurement of oxygen saturation (SO_2) and hemoglobin (HGB)/hematocrit (HCT) levels in human blood. The system is comprised of a system console, laptop computer, optical module and Edwards oximetry catheter. The system console emits light that is transmitted into the blood stream through the optical module that connects to the oximetry catheter. The light is reflected back through the catheter to the system console and the spectral data is used to calculate SO_2 and HGB. The PreSep Oximetry catheter is a catheter that is used with Edwards oximetry monitors to measure oxygen saturation and also provides the means for measuring hemoglobin with the EW200 System.

Intended Use:	The EW200 System is indicated for use in patients requiring monitoring of hemodynamic parameters, including oxygen saturation and hemoglobin. The PreSep catheter is indicated for hemodynamic monitoring through oxygen saturation measurement and hemoglobin measurement.
Comparative Analysis:	The EW200 System and PreSep catheter have been demonstrated to be as safe and effective as the predicate devices for their intended use.
Functional/Safety Testing:	The EW200 System and PreSep catheter have successfully undergone functional testing. In addition, the EW200 System was also subjected to electrical safety testing. These products have been shown to be equivalent to the predicate devices.
Conclusion:	The EW200 System and PreSep catheter are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

Edwards Lifesciences, LLC
c/o Ms. Laura Danielson
TUV Product Service America
1775 Old Highway 8NW, Suite 104
New Brighton, MN 55112

Re: K060660
Trade/Device Name: EW200 System and PreSep Oximetry Catheter
Regulation Number: 21 CFR §870 and 21 CFR §870.1230
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer, and Catheter, Oximeter, Fiberoptic
Regulatory Class: Class II (two)
Product Code: DXG and DQE
Dated: April 25, 2006
Received: April 25, 2006

Dear Ms. Danielson:

This letter corrects our substantially equivalent letter of April 25, 2006.

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 (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.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

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

Enclosure

K060660

Edwards Lifesciences LLC
510(k) Notification for the EW200 System and PreSep Catheter

510(k) Number (if known): K060660

Device Name: EW200 System and PreSep Oximetry Catheter

Indications for Use:

The EW200 System is indicated for use in patients requiring monitoring of hemodynamic parameters, including oxygen saturation and hemoglobin.

The PreSep Oximetry catheter is indicated for hemodynamic monitoring through oxygen saturation measurement and hemoglobin measurement.

Edwards oximetry catheters are indicated for oxygen saturation and hemoglobin measurement.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060660