510(k) Summary

K110167
p 1/2

FEB 18 2011

Submitter: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614-5686

Contact Person: Marguerite Thomlinson, JD, BSME
Sr. Manager of Regulatory Affairs
Edwards Lifesciences LLC
Phone: (949) 756-4386
Fax: (949) 809-5676

Date Prepared: February 17, 2011

Trade Name: PreSep Oligon Oximetry Catheters

Classification Name: Catheter, Oximeter, Fiberoptic (21 CFR Part 870.1230)

Product Class/ Code: Class II/ DQE

Predicate Devices: K060093, PreSep Oligon Oximetry Catheters
K100739, VolumeView System

Device Description:

The PreSep Oligon Oximetry Catheters (K060093) are used with Edwards oximetry monitors to continuously measure oxygen saturation. The catheters also provide the means for infusion of solutions, measuring pressure and taking blood samples. The PreSep Oligon Oximetry Catheters can be used with an uncoated stainless steel guidewire or a PTFE-coated Nitinol core guidewire, which are included in kits or as separately packaged components.

Indications for Use:

The PreSep Oligon Oximetry Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring and oxygen saturation measurements.

Comparative Analysis:

Verification and validation testing was conducted to compare the performance and functionality of the PreSep Oligon Oximetry Catheters to the predicate device. This testing regimen included side-by-side comparative bench and pre-clinical performance testing of the pending and predicate devices. The results show that the

510(k) Summary

K110167
p 2/2

performance functionality of the pending guidewire is substantially equivalent to the predicate device, and provides a marked improvement in the ease of use of the pending device in comparison to the predicate device. Thus, the PreSep Oligon Oximetry Catheters have been demonstrated to be safe and effective and substantially equivalent to the predicate device for their intended use.

Functional/Safety Testing:

The PreSep Oligon Oximetry Catheters have successfully undergone functional and performance testing, including bench studies, pre-clinical animal studies and biocompatibility testing. The PreSep Oligon Oximetry Catheters have been shown to be safe and effective and substantially equivalent to the cited predicate device for their intended use.

Conclusion:

The PreSep Oligon Oximetry Catheters are safe and effective and are 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 Ms. Marguerite Thomlinson
Sr. Manager of Regulatory Affairs, Critical Care
One Edwards Way
Irvine, CA 92614

FEB 18 2011

Re: K110167
Trade/Device Name: PreSep Oligon Oximetry Catheters
Regulation Number: 21 CFR 870.1230
Regulation Name: Catheter, Oximetry, Fiberoptic
Regulatory Class: Class II
Product Code: DQE
Dated: January 18, 2011
Received: January 20, 2011

Dear Ms. Thomlinson:

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.

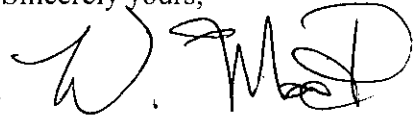
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Indications for Use

510(k) Number (if known): K110167

Device Name: PreSep Oligon Oximetry Catheters

Indications for Use:

The PreSep Oligon Oximetry Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring and oxygen saturation measurements.

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

(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 K110167