



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

June 16, 2016

Edwards Lifesciences, LLC
Deana Boushell
Senior Manager, RA
1 Edwards Way
Irvine, California 92614

Re: K160645

Trade/Device Name: Presep Oligon Oximetry Catheter
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II
Product Code: DQE
Dated: March 4, 2016
Received: March 7, 2016

Dear Deana Boushell:

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

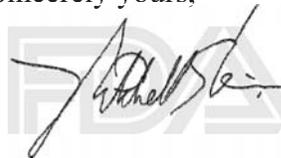
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

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)

K160645

Device Name

PreSep Oligon Oximetry Catheter

Indications for Use (Describe)

The pressure injectable PreSep Oligon Oximetry Catheters are indicated for short term (< 30 days) hemodynamic monitoring through blood sampling, infusion of solutions, continuous monitoring of oxygen saturation measurements, pressure injection of contrast media and central venous pressure monitoring.

When used for pressure injection of contrast media do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable PreSep Oligon Oximetry Catheter may not exceed 400psi.

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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Traditional 510(k) – PreSep Oligon Oximetry Catheters**SECTION 5 – 510(k) SUMMARY**

PreSep Oligon Oximetry Catheter	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Deana Boushell
Date Prepared	June 15, 2016
Trade Name	PreSep Oligon Oximetry Catheter
Classification Name	Catheter, Oximeter, Fiberoptic (21 CFR 870.1230)
Regulation Class/Product Code	Class II/ DQE
Predicate Device(s)	K060093: PreSep Oligon Oximetry Catheters K071538: Arrow G+ Blue Plus Pressure Injectable Central Venous Catheter
Device Description	<p>The PreSep Oligon Oximetry Catheter is a pressure injectable antimicrobial catheter intended to provide the means for infusion of solutions, measuring pressure, delivering contrast media and taking blood samples through the distal, proximal and medial lumens. The PreSep Oligon Oximetry Catheter also provides the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor.</p> <p>The PreSep Oligon Oximetry Catheter is a 3 lumen catheter available in 8.5 French, 16 and 20cm lengths. The lumens exit at the tip of the catheter for the distal; medial and proximal exit at the ports. The catheter is manufactured from a base material of barium sulfate-filled polyurethane. Barium sulfate makes the material more radiopaque. Carbon, silver, and platinum are added to the base material. The silver and platinum render the polymer antimicrobial, by oligodynamic iontophoresis. The antimicrobial agent is silver, which is ionized and electrochemically released from the inside and outside surfaces of the catheter material into the lumens and subcutaneous space. The Oligon polymer technology provides antimicrobial protection on both the inside and outside of the catheter.</p> <p>With the use of the Oligon material, the catheter has demonstrated significant antimicrobial activity, within 48 hours after inoculation, against the following organisms: <i>Staphylococcus epidermidis</i>, <i>Staphylococcus aureus</i>, <i>Enterococcus faecalis</i>, <i>Candida albicans</i>, <i>Escherichia coli</i>, <i>Serratia marcescens</i>, <i>Acinetobacter calcoaceticus</i>, <i>Corynebacterium diphtheriae</i>, <i>Enterobacter aerogenes</i>, <i>Klebsiella pneumoniae</i>, <i>Staphylococcus aureus</i> Gentamicin and Methicillin resistant (GMRSA), <i>Pseudomonas aeruginosa</i>, <i>Candida glabrata</i>, and VRE (<i>Enterococcus faecium</i>)</p>
Indications for Use/Intended Use	The pressure injectable PreSep Oligon Oximetry Catheters are indicated for short term (< 30 days) hemodynamic monitoring through blood sampling, infusion of solutions, continuous monitoring of oxygen saturation

Traditional 510(k) – PreSep Oligon Oximetry Catheters

	<p>measurements, pressure injection of contrast media and central venous pressure monitoring.</p> <p>When used for pressure injection of contrast media do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable PreSep Oligon Oximetry Catheter may not exceed 400psi.</p>
Comparative Analysis	<p>Testing was conducted to confirm the performance and functionality of the PreSep Oligon Oximetry Catheter as compared to the predicate device. There are no design differences between the two devices. The only difference is in the labeling, specifically an indication expansion to include the pressure injection of contrast media and the addition of MR Safe labeling. The PreSep Oligon Oximetry Catheter was shown to be safe, effective, and substantially equivalent to the predicate device for its intended use.</p>
Functional/ Safety Testing	<p>PreSep Oligon Oximetry Catheter has successfully passed functional and performance testing, including blood oxygenation, tensile, fatigue, flow rate, tip buckling, radiopacity, pressure, silver release and MRI testing.</p>
Conclusion	<p>PreSep Oligon Oximetry Catheter has been shown to be safe, effective, and is substantially equivalent to the predicate for its intended use.</p>