February 20, 2018

Edwards Lifesciences LLC
Bedalin Lugo Rodriguez
Sr. Regulatory Affairs Specialist
One Edwards Way
Irvine, California 92614

Re: K172423
Trade/Device Name: Edwards Oximetry Central Venous Catheter (EOCVC), Edwards Oligon Oximetry Central Venous Catheter, PediaSat Oximetry Catheter
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II
Product Code: DQE, DRE
Dated: January 10, 2018
Received: January 17, 2018

Dear Bedalin Lugo Rodriguez:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172423

Device Name
Edwards Oximetry Central Venous Catheter (EOCVC), Edwards Oligon Oximetry Central Venous Catheter and PediaSat Oximetry catheters

Indications for Use *(Describe)*
The EOCVC Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring, and oxygen saturation measurements.

PediaSat Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring, and oxygen saturation measurements in adults and/or pediatric patients.

The pressure injectable EOCVC Oligon 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.

The suture loop and box clamp are intended to be used to facilitate the suturing the catheter at the site of insertion.

The dilator, included with each catheter, is indicated for enlarging the opening in a vessel for preparation of percutaneous entry of the catheter.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

SECTION 5.0 – 510(K) SUMMARY

Table 5.1: EOCVC and PediaSat Oximetry Catheters	
510(K) Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Bedalin Lugo Rodriguez Sr. Regulatory Affairs Specialist Critical Care One Edwards Way Irvine, CA 92614 Bedalin_lugo@edwards.com Phone: 787-229-5433, fax 949-809-2967
Date Prepared:	February 19, 2018
Trade name:	Edwards Oximetry Central Venous Catheter (EOCVC), Edwards Oligon Oximetry Central Venous Catheter, PediaSat Oximetry Catheters
Classification Name:	Fiber Optic Oximeter Catheter (21 CFR 870.1230) Dilator, Vessel, For Percutaneous Catheterization (21 CFR 870.1310)
Regulation Class/ Product Code:	Class II/ DQE, DRE
Predicate Device(s):	K053609: PreSep (now EOCVC) & PediaSat Oximetry Catheters (Primary Predicate) K160645: PreSep (now EOCVC) Oligon Oximetry Catheter (Secondary Predicate)
Device Description:	The Edwards Oximetry Central Venous Catheter is a non-balloon catheter that provides the means for infusion of solutions, measuring pressure, and taking blood samples through the distal lumen (terminates at the catheter tip), the proximal lumen (terminates 7 cm proximal to the tip), and the medial lumen (terminates 5 cm proximal to the tip). Edwards Oximetry Central Venous Catheter also provides the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor or compatible bedside module. The PediaSat oximetry catheters are non-balloon catheters that provide the means for infusion of solutions, measuring pressure, and taking blood samples. These catheters also provide the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor or compatible bedside module. The EOCVC Oligon catheter is a non-balloon catheter that provides the means for infusion of solutions, measuring pressure,

Table 5.1: EOCVC and PediaSat Oximetry Catheters	
	injecting contrast media, and taking blood samples through the distal lumen (terminates 7 cm proximate to the tip), and the medial lumen (terminates 5 cm proximal to the tip). The EOCVC Oligon catheter also provides the means for continuously monitoring oxygen saturation using an Edwards Lifesciences monitor and compatible bedside module. All catheters are manufactured with a polyurethane-based Oligon polymer (containing silver, platinum, and carbon black) which has antimicrobial properties. Oxygen saturation is monitored by fiberoptic reflectance spectrophotometry. The amount of light absorbed, refracted, and reflected depends on the relative amounts of oxygenated and deoxygenated hemoglobin in the blood. The PediaSat Oximetry Catheter is a 3 lumen catheter available with a diameter of 4.5 French (F) and 8 cm in length. The EOCVC Oximetry Catheters are 3 lumen catheters available with a diameter of 8.5F and in lengths of 16 and 20 cm. EOCVC and PediaSat catheters are manufactured from polyurethane. A suture loop and a specially molded box clamp are provided with each EOCVC (Oligon and non-Oligon) and PediaSat Oximetry Catheter to facilitate suturing of the catheter at the site of insertion. The suture loop and box clamp can be placed anywhere along the catheter body at the discretion of the clinician. The dilator, included with each catheter, is indicated for enlarging the opening in a vessel for preparation of percutaneous entry of the catheter. The EOCVC (Oligon and non-Oligon) and PediaSat Kits consist of accessories previously cleared for marketing as well as accessories that are the subject of this submission. This submission is for clearance of proposed modifications to the accessories (suture loop, box clamp and dilator) for use with the previously cleared EOCVC Oligon (K160645), PreSep (now EOCVC), and PediaSat (K053609) Oximetry Catheter Kits. Additional accessories are listed on table below.
Indications for use/Intended Use:	The EOCVC Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring, and oxygen saturation measurements. PediaSat Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring, and oxygen saturation measurements in adults and/or pediatric patients. The pressure injectable EOCVC Oligon catheters are indicated for short term (< 30 days) hemodynamic monitoring through blood

Table 5.1: EOCVC and PediaSat Oximetry Catheters	
	sampling, infusion of solutions, continuous monitoring of oxygen saturation measurements, pressure injection of contrast media, and central venous pressure monitoring. The suture loop and box clamp are intended to be used to facilitate the suturing the catheter at the site of insertion. The dilator, included with each catheter, is indicated for enlarging the opening in a vessel for preparation of percutaneous entry of the catheter.
Comparative Analysis:	Testing was conducted to compare the performance and functionality of the EOCVC (Oligon and non-Oligon) and PediaSat Oximetry Catheter accessories to the predicate device accessories. The accessories to the EOCVC (Oligon and non-Oligon) and PediaSat Oximetry Catheters were shown to be safe, effective, and substantially equivalent to the predicate device for its intended use.
Functional/Safety Testing:	The accessories to the EOCVC (Oligon and non-Oligon) and PediaSat Oximetry Catheters have successfully passed functional and performance testing, including biocompatibility and bench testing that includes visual inspection, tensile strength, retention force, insertion test, guidewire passage and dimensional verifications.
Conclusion:	Test data established that the proposed modifications to accessories have been shown to be equivalent to the predicate devices for their intended use.