DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 28, 2016

Edwards Lifesciences LLC
Jennifer Wilbur
Manager, Critical Care Regulatory Affairs, Program Management
One Edwards Way
Irvine, California 92614

Re: K161962
Trade/Device Name: VAMP Venous/Arterial Blood Management Protection System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 26, 2016
Received: October 27, 2016

Dear Jennifer Wilbur:

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.

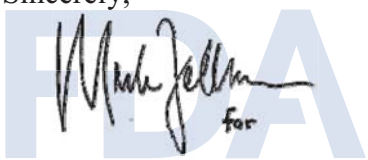
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161962

Device Name
VAMP Venous/Arterial Blood Management Protection System

Indications for Use *(Describe)*

VAMP Adult and VAMP Plus:

To be used only for blood withdrawal.

The blood sampling system is indicated for use on patients requiring periodic withdrawal of blood samples from arterial and central line catheters, including peripherally inserted central catheters and central venous catheters, which are attached to pressure monitoring lines.

VAMP Jr.:

To be used only for blood withdrawal.

The blood sampling system is indicated for use on pediatric patients (including neonates) requiring periodic withdrawal of blood samples from umbilical, arterial and central line catheters, including peripherally inserted central catheters and central venous catheters, which are attached to pressure monitoring lines.

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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SECTION 5 – 510(k) SUMMARY

510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	**Primary Contact** Jennifer Wilbur Manager, Regulatory Affairs, PM Jennifer_Wilbur@edwards.com Office: 949-756-4436 Cell: 508-776-4525 Fax: 949-809-2984 **Anticipated to be on maternity leave from November 17, 2016 – February 8, 2017**	**Backup Contact** Deana Boushell Senior Manager, Regulatory Affairs, PM Deana_Boushell@edwards.com Office: 949-756-4472 Cell: 508-254-3289 Fax: 949-809-2967
Date Prepared	November 23, 2016	
Trade Name	VAMP Venous/Arterial Blood Management Protection System	
Common Name	Closed Blood Sampling System	
Classification Name	Catheter, Continuous Flush (CFR 21 870.1210)	
Regulation Class/Product Code	Class II KRA	
Predicate Device(s)	K885281: VAMP Venous/Arterial Blood Management Protection System	
Device Description	The subject Edwards Venous/Arterial Blood Management Protection (VAMP) System is a sterile, single use device that provides a safe and convenient method for the withdrawal of blood samples when attached to pressure monitoring lines. The subject device is a needleless closed blood sampling system designed to reduce infection, needle sticks, and blood waste associated with blood sampling. The VAMP blood sampling system is designed for use with disposable and reusable pressure transducers and for connection to central line catheters (inclusive of peripherally inserted central catheters and central venous catheters), arterial catheters, and umbilical catheters where the system can be flushed clear after sampling. The VAMP blood sampling system is used for the drawing and retention of heparinized/diluted blood (or clearing volume) from the catheter or cannula within the line, allowing undiluted blood samples to be drawn from an in-line sampling site. At the completion of sample draw, the mixed heparin and blood solution (clearing volume) is reinfused into the patient to reduce fluid loss to the patient. The collected blood can be transferred to a vacuum tube via a VAMP Blood Transfer Unit (BTU) or a VAMP Direct-Draw unit. The main purpose of the BTU is to provide a conduit (split septum membrane) in which a blood-filled syringe and blunt cannula assembly can transfer the blood sample to a vacuum tube without using a needle. The Direct-Draw Unit performs in the	

	same fashion, except it allows for direct connection of the vacuum tube and doesn't require use of separate sampling syringe.
Indications for Use/Intended Use	<u>VAMP Adult and VAMP Plus</u> To be used only for blood withdrawal. The blood sampling system is indicated for use on patients requiring periodic withdrawal of blood samples from arterial and central line catheters, including peripherally inserted central catheters and central venous catheters, which are attached to pressure monitoring lines. <u>VAMP Jr.</u> To be used only for blood withdrawal. The blood sampling system is indicated for use on pediatric patients (including neonates) requiring periodic withdrawal of blood samples from umbilical, arterial and central line catheters, including peripherally inserted central catheters and central venous catheters, which are attached to pressure monitoring lines.
Comparative Analysis	There are no physical differences between the subject and predicate devices. The proposed changes to the predicate device include an update to the indications of VAMP Adult, VAMP Plus and VAMP Jr. to clarify that central line catheters are inclusive of central venous catheters and peripherally inserted central catheters. This clarification has no impact to the intended use and is only serving to clarify what is meant by central line catheter.
Functional/ Safety Testing	The VAMP blood sampling system has successfully passed MRI safety testing.
Conclusion	The Edwards Venous/Arterial Blood Management Protection System and its accessories have been demonstrated to be substantially equivalent to the predicate Venous/Arterial Blood Management Protection System and its accessories (K885281).