April 5, 2018

Edwards Lifesciences, LLC
Ye Kim
Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92618

Re: K173586
Trade/Device Name: VAMP Venous/Arterial Blood Management Protection System (VAMP Adult)
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 2, 2018
Received: March 5, 2018

Dear Ye Kim:

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,

Kenneth J. Cavanaugh -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173586

Device Name
VAMP Venous/Arterial Blood Management Protection System

Indications for Use *(Describe)*
VAMP Adult blood sampling system:

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.

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.

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SECTION 5 – 510(k) SUMMARY K173586

510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	**Primary Contact** Ye Seul Kim Specialist, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 2445 Fax: (949) 809 – 5425 Email: yeseul_kim@edwards.com	**Secondary Contact** Renate MacLaren Senior Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 5783 Fax: (949) 809 – 2941 Email: renate_maclaren@edwards.com
Date Prepared	April 5, 2018	
Trade Name	VAMP Venous/Arterial Blood Management Protection System	
Common Name	Closed Blood Sampling System	
Classification Name	Catheter, Continuous Flush (21 CFR 870.1210)	
Regulation Class/Product Code	Class II KRA	
Primary Predicate Device	K161962: VAMP Venous/Arterial Blood Management Protection System (Cleared on November 28, 2016)	
Secondary Predicate Device	K171996: TruWave™ Disposable Pressure Transducer and associated kits (Cleared on October 23, 2017)	
Device Description	The Edwards Venous/Arterial Blood Management Protection (VAMP) Systems are sterile, single use devices that provide a safe and convenient method for the withdrawal of blood samples when attached to pressure monitoring lines. The VAMP devices are needleless closed blood sampling systems designed to reduce infection, needle sticks, and blood waste associated with blood sampling. One family of VAMP product line, the VAMP Adult blood sampling system, is the subject of this submission. The VAMP Adult 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) and arterial catheters where the system can be flushed clear after sampling. The VAMP Adult 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.	

Indications for Use/Intended Use	VAMP Adult 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.
Comparative Analysis	The subject device is identical to the predicate devices in terms of intended use/ indications for use, and technology. The proposed changes to the device include a change of sterilization method (100% Ethylene Oxide to E-beam radiation); change in the PVC plasticizer from DEHP to the non-phthalate plasticizer, Cyclohexane-1, 2-dicarboxylic acid diisononyl ester (DINCH®) for the tubing; update of product labeling to reflect changes in sterilization method (from EO to E-beam radiation) and removal of phthalate symbol on all levels of packaging; introduction of an additional sampling site, Luer Activated Sampling Site (K060231) to replace the z-site in some of the VAMP Adult models. Testing was conducted to ensure that the change in sterilization method and change in materials did not alter the performance of the VAMP Adult blood sampling system. The subject VAMP Adult blood sampling system has been shown to be substantially equivalent to the predicate devices for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The VAMP Adult blood sampling system has successfully passed functional and performance testing, including packaging, shelf life, sterilization, biocompatibility, chemical characterization and bench testing that includes overpressure leak testing, negative leak testing, pressure tubing pull testing and frequency response testing.
Conclusion	The VAMP Adult blood sampling system is substantially equivalent to the predicate devices, the Venous/Arterial Blood Management Protection Systems (K161962) and the TruWave™ Disposable Pressure Transducer and associated kits (K171996).