October 24, 2018

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

Re: K180275
Trade/Device Name: VAMP Optima closed blood sampling system
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 30, 2018
Received: January 31, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Fernando Aguel -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180275

Device Name
VAMP Optima closed blood sampling system

Indications for Use *(Describe)*

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

510(k) Submitter	Edwards Lifesciences, LLC
Establishment Registration Number	2015691
Address	One Edwards Way Irvine, CA 92614 Phone: 949-250-2500
Contact Person	Jennifer Wilbur Manager, Regulatory Affairs Program Management Edwards Lifesciences One Edwards Way Irvine, CA 92614 Email: Jennifer_Wilbur@edwards.com Office: 949-756-4436 Fax: 949-809-2984
Date Prepared	January 30, 2018
Trade Name	VAMP Optima closed blood sampling system
Common Name	Closed Blood Sampling System
Classification Name	Catheter, Continuous Flush (21 CFR 870.1210) Stopcock, I.V. Set and Intravascular administration set (21 CFR 880.5440)
Regulation Class/Product Code	Class II KRA, FMG, FPA
Predicate Device(s)	K161962: VAMP Plus Venous/Arterial Blood Management Protection System
Device Description	The subject Edwards Lifesciences VAMP Optima closed blood sampling system is a sterile, single-use device that provides a safe and convenient method for the withdrawal of blood samples from 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 Optima closed blood sampling system is designed for use with disposable 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 Optima closed blood sampling system is used for the drawing and retention of heparinized or non-heparinized blood 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 drawing, the blood or mixed heparin and blood solution is reinfused into the patient to reduce fluid loss.

<table>
<tr><td>Indications for Use/Intended Use</td><td>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.</td></tr>
<tr><td>Models</td><td>VAMP Optima closed blood sampling system models
<table>
<tr><th>Model Number</th><th>Model Description</th></tr>
<tr><td>VOPTIMA</td><td>VAMP Optima with Z-site + COMBICAP caps, 10-pack</td></tr>
<tr><td>VOPTIMAL</td><td>VAMP Optima with LASS + COMBICAP caps, 10-pack</td></tr>
<tr><td>MHD8VZ</td><td>FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, single pack</td></tr>
<tr><td>MHD8VZ5</td><td>FloTrac sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, 5-pack</td></tr>
<tr><td>MHD8VRL</td><td>FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack</td></tr>
<tr><td>MHD8VRL5</td><td>FloTrac sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red stopcock inserts + red striped tubing, 5-pack</td></tr>
<tr><td>MHD8VZTW</td><td>FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with Z-site, + COMBICAP caps + blue striped tubing, 5-pack</td></tr>
<tr><td>MHD8VLTW</td><td>FloTrac sensor + IV Set + TruWave DPT + VAMP Optima with LASS + COMBICAP caps + red striped tubing + blue striped tubing, 5-pack</td></tr>
<tr><td>MHDQ8VZ</td><td>FloTrac IQ sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, single pack</td></tr>
<tr><td>MHDQ8VZ5</td><td>FloTrac IQ sensor + IV Set + VAMP Optima with Z-site + COMBICAP caps, 5-pack</td></tr>
<tr><td>MHDQ8VRL</td><td>FloTrac IQ sensor + IV Set + VAMP Optima with LASS + COMBICAP caps + red striped tubing, single pack</td></tr>
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</table></td></tr>
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Comparative Analysis	The modified VAMP Optima closed blood sampling system has the following similarities to the predicate VAMP Plus device: • has the same indications for use, intended use and contraindications, • uses the same operating principle, • has similar technological characteristics, • built from the same type of components, • incorporates the same basic reservoir design, • utilizes many of the same materials, • includes the option for a Z-site sample site, • is MR Conditional, • contains an IV set, • compatible with a TruWave disposable pressure transducer (K142749), • is packaged and sterilized using the same materials and processes The following proposed changes from the VAMP Plus to the VAMP Optima closed blood sampling system are the subject of this 510(k) submission. These differences are not a fundamental change in scientific technology and have no impact to the intended use or indications for use. • Expansion of sampling site offerings beyond the current Z-site to include a needleless Luer Access Sample Site (LASS), • Modification to subassembly components: o Modification from a two position one-way valve to a four position three-way valve o Modification to the reservoir from a one port to a two port syringe body in order to align with the three-way valve design o Dimensional and cosmetic modifications to the reservoir and reservoir bracket • Pressure tubing, IV Set and adhesive material changes, • Male luer lock connector change, • Designed to be compatible with a FloTrac sensor (K152980)
Functional/ Safety Testing	The VAMP Optima closed blood sampling system has successfully passed functional and performance testing, including packaging, shelf life, sterilization, biocompatibility, chemical characterization, human factors, pre-clinical testing and bench studies. Testing was performed in accordance with the following standards: ISO 10993-1, ISO 11607-1/-2, ISO 11135, ASTM F2503-13 and FDA's 2008 device-specific guidance "Intravascular Administration Sets Premarket Notification Submissions [510(k)]."
Conclusion	The Edwards Lifesciences VAMP Optima closed blood sampling system has been demonstrated to be substantially equivalent to the predicate VAMP Plus Venous/Arterial Blood Management Protection System (K161962).