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

May 24, 2017

Smiths Medical ASD, Inc.
James Taufen
Director, Regulatory Affairs
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K163172
Trade/Device Name: HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Transducer System; HemoDraw® Plus Closed Blood Sampling Set with TranStar® Transducer System
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: April 21, 2017
Received: April 24, 2017

Dear Bruce Backlund:

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,

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)*
K163172

Device Name
HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Transducer System
HemoDraw® Plus Closed Blood Sampling Set with TranStar® Transducer System

Indications for Use *(Describe)*

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system. This device is for use in adults only.

The HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system. This device is for use in adults only.

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.

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"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."

510(k) Summary of Safety and Effectiveness

I. Administrative Information

Applicant's Name and Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Jim Taufen Director Regulatory Affairs
Phone	763-383-3174
Fax	763-383-3679
Email	James.Taufen@smiths-medical.com
Date Prepared	23-May-2017

II. Device Information

Trade Name	HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Transducer System HemoDraw® Plus Closed Blood Sampling Set with TranStar® Transducer System
Common Name	Closed Blood Sampling System
Classification Name	Extravascular Blood Pressure Transducer, 21 CFR § 870.2850 Product Code DRS

III. Predicate Device Information

Predicate Device Name	**Predicate Device 510(k) Number**
HemoDraw Arterial Blood Sampling System	K071269
VAMP Venous/Arterial Blood Management Protection	K885281

IV. Device Description

The HemoDraw® Arterial Blood Sampling System was cleared (K071269 S.E. August 1, 2007) to be used with Logical® and TranStar® pressure transducers that had been previously cleared K961404 S.E. June 27, 1996 and K942377 S.E. August 16, 1994, respectively. Their descriptions are as follows:

HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System

The HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System is a closed blood Sampling System designed to allow easy and safe withdrawal of blood samples from an arterial and central venous invasive pressure monitoring line.

The LogiCal® Pressure Transducer mounting plate is intended for uses with the HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System. The LogiCal® disposable monitoring set provides isolation between the fluid path connection to the patient and the transducer diaphragm.

This set includes a flush device that is intended for use in invasive blood pressure measurements that require continuous flow to maintain catheter patency. The flush device provides a controlled and constant fluid infusion at a rate determined by the patient's blood pressure and the fluid source pressure. With a total fluid source pressure equal to 300mmHg, the flush device delivers an average flow rate of 3ml/hour.

The device is supplied with a vented cap on the zeroing stopcock; this vented cap will allow air and saline to pass through and therefore can be kept in place when priming. To prevent the introduction of air into the system; after priming the vented cap should be replaced with a non-vented cap.

This device is intended for single use only and is provided sterile and fluid path non-pyrogenic unless package is damaged or opened.

HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System is a closed blood Sampling System designed to allow easy and safe withdrawal of blood samples from an arterial and venous invasive pressure monitoring line.

The TranStar® Pressure Transducer mounting plate is intended for uses with the HemoDraw® Closed Blood Sampling Set with TranStar® Pressure Monitoring System. The LogiCal® disposable monitoring set provides isolation between the fluid path connection to the patient and the transducer diaphragm.

This set includes a flush device that is intended for use in invasive blood pressure measurements that require continuous flow to maintain catheter patency. The flush device provides a controlled and constant fluid infusion at a rate determined by the patient's blood pressure and the fluid source pressure. With a total fluid source pressure equal to 300mmHg, the flush device delivers an average flow rate of 3ml/hour.

The device is supplied with a porous plug on the zeroing stopcock; this porous plug will allow air and saline to pass through and therefore can be kept in place when priming. To prevent the introduction of air into the system; after priming the porous plug should be replaced with a non-vented cap.

This device is intended for single use only and is provided sterile and fluid path non-pyrogenic unless package is damaged or opened**.**

V. Indications for Use

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system. This device is for use in adults only.

The HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system. This device is for use in adults only.

VI. Comparative Analysis

There are minor physical differences between the subject and predicate devices. The physical differences are a material change to the HemoDraw syringe tip and a new needless sample port. The proposed changes to the predicate device further include an update to the indications of the HemoDraw Arterial Blood Sampling System to include blood sample withdrawal from the central venous pressure monitoring line.

VII. Technological Characteristics

The Smiths Medical HemoDraw® Plus Closed Blood Sampling System has the same technological characteristics as the predicate devices with the exception that the proposed version introduces a new needleless sampling port to the existing legally marketed predicate devices.

Factors	**HemoDraw® Plus CBSS with TranStar® or LogiCal® Pressure Monitoring System**	**HemoDraw® Arterial Blood Sampling Set**	**Edwards Lifesciences VAMP**
Intended Use and Claims			
Same intended use	Similar	Similar	Similar
Same target population	Yes	Yes	Yes
Sharps prevention device	Yes	Yes	Yes
Sequence of Operation	Yes	Yes	Yes
Technological Features			
Same technological features	Yes	Yes	Yes
Materials			
Reservoir Housing	Polycarbonate	Polycarbonate	Unknown
Septum Housing	Silicone	Synthetic Polyisoprene	Synthetic Polyisoprene
Tubing	PVC	PVC	PVC
Specifications			
EtO Sterilized	Yes	Yes	Yes

Sterile, single use	Yes	Yes	Yes

VIII. Summary of Non-Clinical Testing

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® and LogiCal® Pressure Monitoring Systems were evaluated via non-clinical performance testing to demonstrate the devices are as safe, as effective, and perform as well as or better than the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the HemoDraw® Plus Closed Blood Sampling Set with TranStar® and LogiCal® Pressure Monitoring Systems performed as intended. A summary of the evaluation is provided below.

Category	**Evaluation**
Biocompatibility	- Acute Systemic Toxicity - Intracutaneous Toxicity - Muscle Implantation Test - Cytotoxicity – MEM Elution - Hemolysis – Extraction and Direct - Physico-Chemical Tests - Heavy Metal Analysis - Pyrogen Study - Sensitization - Mutagenicity, Ames Test – Ethanol & Saline
Packaging	The existing packaging materials and processes for the currently marketed devices will be used for the new configurations, for details reference Section 14.3 and Appendix 7 of K071269 S.E. August 1, 2007 which further references K070340 S.E. March 15, 2007 Section 14.3 and Appendix 8. With the addition of the NP Medical sampling port testing was completed for package performance after climatic stress and simulated distribution. The following test was conducted using a worst case packaging configuration: - Visual Package Integrity

Category	Evaluation
Device Performance	- Leakage - Pressure Containment - Cycle Test - Vacuum - Frequency Response - Assembly

Biological and Bench testing was conducted to the following Standards:

Standards Development Organization	Reference Number and Date	Title
ISO	10993-1:2010	Biological evaluation of medical devices Part 1: Evaluation and testing
ISO	10993-7:2008	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO	594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO	594-2:1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
AAMI ANSI ISO	11737-1:2006	Sterilization of Medical Devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products, 2ed

IX. Substantial Equivalence Conclusion

The proposed Smiths Medical HemoDraw® Plus Closed Blood Sampling Set with TranStar® and LogiCal® Pressure Monitoring Systems are substantially equivalent to the predicate devices based on comparisons of the device classifications, intended use, and technological characteristics.