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

June 30, 2016

Smiths Medical ASD, Inc.
Mr. Brian Farias
Principal Regulatory Affairs Specialist
201 West Queen Street
Southington, Connecticut 06489

Re: K160235
Trade/Device Name: ViaValve® Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 31, 2016
Received: June 1, 2016

Dear Mr. Farias:

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" (21CFR 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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K160235

Device Name
ViaValve® Safety I.V. Catheter

Indications for Use *(Describe)*
A properly placed ViaValve® Safety I.V. Catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids. The needle guard locks over the needle as the catheter is threaded into the vessel to help reduce the risk of accidental needlesticks. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 18 to 24 gauge catheters may be used with power injectors up to 300 PSI.

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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K160235

510(k) Summary

I Submitter:

Smiths Medical ASD, Inc.
201 West Queen Street
Southington, CT 06489
Registration Number: 1219611

Contact: Brian D. Farias
Principal Regulatory Affairs Specialist
(603) 352-3812, ext 2493

Summary Prepared: 27 May 2016

II Device Name:

Trade Name: ViaValve® Safety I.V. Catheter
Common Name: Peripheral I.V. Catheter
Classification Name: 880.5200 Intravascular catheter
Regulatory Class II
Product Code FOZ

III Predicate Device(s):

K113700 ViaValve® Safety I.V. Catheter - Smiths Medical ASD, Inc.

IV Device Description:

The ViaValve® Safety I.V. Catheter provides access to a vein or artery. The ViaValve® Safety I.V. Catheter incorporates a valve inside the catheter hub which is designed to reduce blood exposure during initial catheter placement. The valve will open and allow flow once the Luer connector is attached and will remain open after initial activation. The needle assembly incorporates a needle guard which locks over the needle as the ViaValve® Safety I.V. Catheter is threaded into the vessel to help reduce the risk of accidental needlesticks.

V Indications for Use:

A properly placed ViaValve® Safety I.V. Catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids. The needle guard locks over the needle as the catheter is threaded into the vessel to help reduce the risk of accidental needlesticks. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 18 to 24 gauge catheters may be used with power injectors up to 300 PSI.

VI Comparison of Technological Characteristics with the Predicate Device:

The intended use and the technological characteristics of the proposed and predicate devices are the same. The difference is that the proposed device is manufactured with a different polyurethane catheter tubing material. The following table provides a comparison between the subject and predicate device:

	Subject Device ViaValve® Safety I.V. Catheter	**Predicate Device ViaValve® Safety I.V. Catheter**
CHARACTERISTIC		
Peripheral I.V. Catheter	Yes	Yes
Intended Use	Same	Same
Target population	Same	Same
Integral sharps prevention feature	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Single Use	Yes	Yes
Prescription Device	Yes	Yes
Packaging	Form/Fill/Seal Blister Pack	Form/Fill/Seal Blister Pack
One-handed safety activation	Yes	Yes
Use with Power Injectors up to 300 PSI	Yes	Yes
Nonpyrogenic	Yes	Yes
Radiopaque	Yes	Yes
Made with natural rubber latex	No	No
Gauge sizes offered	16G to 24G	14G to 24G
COMPONENTS		
Needle Point Type	V-point	V-point
"Ribbed" Catheter Hub	Yes	Yes
Notched needle cannula for flashback detection	Yes, 20 to 24 gauge sizes	Yes, 20 to 24 gauge sizes
End Cap	Yes	Yes
Has a blood control valve or septum to reduce blood flow during initial catheter placement	Yes	Yes
Blood control valve is permanently open after initial Luer connection is made	Yes	Yes
MATERIALS		
Needle Cannula	304 Stainless Steel	304 Stainless Steel
Catheter Valve or Septum	Silicone Rubber	Silicone Rubber
Catheter Hub	Polypropylene	Polypropylene
Catheter Tube	**Techrilon® Polyurethane**	**Ocrilon® Polyurethane**
End Cap	Polycarbonate	Polycarbonate
Actuator	305 Stainless Steel	305 Stainless Steel

VII Non-Clinical Performance Data:

Bench testing, biocompatibility testing and ISO standard compliance testing as listed below confirms that the ViaValve® Safety I.V. Catheter with Techrilon® polyurethane tubing is substantially equivalent to the Smiths Medical predicate device. Clinical data was not required to demonstrate substantial equivalence.

Biological Testing was conducted as listed below:

E N ISO 10993-5	Cytotoxicity
EN ISO 10993-10	Sensitization
E N ISO 10993-10	Irritation or lntracutaneous reactivity
E N ISO 10993-11	Systemic Toxicity (acute}
EN ISO 10993-11	Subacute and subchronic toxicity
E N ISO 10993-3	Genotoxicity
E N ISO 10993-6	Implantation
EN ISO 10993-4	Hemocompatibility
E N ISO 10993-7	Ethylene Oxide Sterilization Residuals
EN ISO 10993-17	Risk Assessment
EN ISO 10993-18	Chemical Characterization of Materials

Bench Testing was conducted to the following Standards:

Standard	Title
ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements Tests: •Gauging •Liquid and Air Leakage •Separation Force • Stress Cracking
ISO 594-2:1998(E)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment –Part2:Lock Fittings Tests: •Gauging •Liquid and Air Leakage •Separation and Unscrewing Force •Ease of Assembly •Resistance to Overriding •Stress Cracking
ISO 10555-1:2013 (Corrected version 2013-07-01)	Intravascular catheters-Sterile and single- use catheters- Part 1: General requirements Tests: •Radio-detectability •Biocompatibility •Surface •Corrosion resistance

	•Peak tensile force •Hub connections •Flowrate •Power injection •Distal tip
ISO 10555-5:2013	Intravascular catheters-Sterile and single- use catheters- Part5: Over-needle peripheral catheters Tests: •Cather tip conformance •Needle point and hub •Strength of Union •Vent Fitting •Flowrate
ISO 23908:2011	Sharps Injury protection-Requirements and test methods- Sharps protection features for single-use hypodermic needles. Introducers for catheters and needles used for blood sampling. Tests: •Sharps activation •Security of safe mode • Challenging device in safe mode •Testing access of the device in safe mode •Testing simulated clinical use

VIII Conclusions:

Based on the indications for use, technological characteristics, and performance testing, the subject ViaValve® Safety I.V. Catheter is demonstrated to be substantially equivalent to the predicate device.