May 17, 2018

Smiths Medical ASD, Inc.
Sunny Teekasingh
Principal Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K172592
Trade/Device Name: CADD Yellow High Volume Administration Set with NRFit connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: PWH
Dated: April 18, 2018
Received: April 19, 2018

Dear Sunny Teekasingh:

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,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172592

Device Name

CADD® Yellow High Volume Administration Set with NRFit™ connector

Indications for Use *(Describe)*

CADD® Yellow High Volume Administration Sets with NRFit™ connectors are designed for use only with NRFit™ components for delivery of regional anesthetics or narcotics, excluding subarachnoid/spinal block, and are designed for use with CADD® pumps (see CADD® pump Operator's Manual for compatibility).

The intended population is pediatrics and adults.

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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1. ADMINISTRATIVE INFORMATION

510(k)	K172592
Applicant's Name and Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Sunny Teekasingh Principal Regulatory Affairs Specialist Phone: 763-383-3336 Fax: 763-383-3679 Email: Sunny.Teekasingh@smiths-medical.com
Date	May 10, 2018
Regulation No.	21 CFR § 880.5440
Regulation Name	Intravascular Administration Set
Primary Product Codes	PWH
Trade Name	CADD® Yellow High Volume Administration Set with NRFit™ connector

2. REASON FOR SUBMISSION

The purpose of this submission is to make a modification to the currently marketed Smiths Medical CADD® High Volume Administration Sets which are being updated to include an ISO 80369-6 compliant connector for regional anesthetic applications.

3. DEVICE INFORMATION

	Predicate Device	Subject Device
Trade Name	CADD® High Volume Administration Set with Flow Stop	CADD® Yellow High Volume Administration Set with NRFit™ connector
Regulation No.	21 CFR § 880.5440	21 CFR § 880.5440
Regulation Name	Intravascular Administration Set	Intravascular Administration Set
Regulatory Class	II	II
Product Code	FPA	PWH
510(k)	K031361	K172592

4. DEVICE DESCRIPTION

The CADD® Yellow High Volume Administration Set with NRFit™ connector device is designed to deliver local or regional anesthetics, narcotics indicated for regional anesthetic infusion applications. The CADD® Yellow High Volume Administration Set with NRFit™ connector consists of components that have a non-Luer taper that allows connection of compatible components that, when used together as a system, help reduce the risk of misconnection that may result in the infusion of medications not intended for regional anesthetic or narcotic delivery.

The NRFit™ connector of the neuraxial ISO 80369-6 compliant non-Luer system is incompatible with standard Luer tapers; therefore, the two systems cannot mate together effectively. The NRFit™

connectors conform to ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications*. The connectors are not compatible with standard luer connectors which is intended to reduce the risk of misconnection that may result in the infusion of medications not intended for regional anesthetic or narcotic delivery.

The CADD® Yellow High Volume Administration Set with NRFit™ connector devices are color-coded yellow to indicate medication intended for regional anesthetic delivery.

All CADD® Yellow High Volume Administration Set with NRFit™ connector devices are intended for prescription use only.

5. INDICATIONS FOR USE

The Smiths Medical CADD® Yellow High Volume Administration Set with NRFit™ connectors are intended for use only with NRFit™ components for delivery of regional anesthetics or narcotics, excluding subarachnoid / spinal block, and are designed for use with CADD® pumps (see CADD® pump Operator's Manual for compatibility). The intended population is pediatrics and adults.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Smiths Medical CADD® Yellow High Volume Administration Set with NRFit™ connectors have the same technological characteristics as the predicate devices with the exception of the NRFit™ Connectors.

The Smiths Medical CADD® Yellow High Volume Administration Set with NRFit™ connectors and predicate devices are both designed to deliver local or regional anesthetics or narcotics, indicated for regional anesthetic infusion applications. They are both made of the same materials, have the same chemical composition, and have the same design features excluding the NRFit™ connector design.

The Smiths Medical CADD® Yellow High Volume Administration Set with NRFit™ connectors utilize connectors that comply with ISO 80369-6. These connectors are intentionally designed to be incompatible with Luer tapers such as those found on the predicate devices to mitigate the risks associated with connecting infusion lines to the incorrect infusion pump. The predicate devices utilize standard Luer connectors that comply with ISO 594, *"Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment."* A side-by-side characteristic analysis of Predicate and Subject Device is provided in **Table 1.**

Table 1: Comparative Analysis of Subject and Predicate Devices by Characteristic

Characteristic	Subject Device K172592	Predicate Device K031361	Discussion
Indications	CADD® Yellow High Volume Administration Set with NRFit™ connectors are intended for use only with NRFit™ components for delivery of regional anesthetics or narcotics, excluding subarachnoid / spinal	CADD® High-Volume Administration Sets is designed for use with the CADD-Prism® pump to allow fluid delivery from an IV bag.	Both used with CADD pump.

Characteristic	Subject Device K172592	Predicate Device K031361	Discussion
	block, and are designed for use with CADD® pumps (see CADD® pump Operator's Manual for compatibility). The intended population is pediatrics and adults.		
Sterility Method	EO	EO	Same
Single use	Yes	Yes	Same
Disposable	Yes	Yes	Same
Prescription	Yes	Yes	Same
Connections	**ISO 80369-6 compliant NRFit™ non-Luer connectors**	**ISO 594 Luer tapers**	**The NRFit™ connector provides the same clinical function (i.e., secure, non-leaking connection), but incorporates the ISO 80369-6 connector design to mitigate the risk of misconnections.**
Model: CADD® High Volume Administration Sets (with Air-Eliminating Filter and Flow Stop Free-Flow Protection)	21-7685-24	21-7385-24	N/A
Model: CADD® High Volume Administration Sets (with Flow Stop Free-Flow Protection)	21-7684-24	21-7384-24	N/A
Nominal Set Length	130 inches	130 inches	Same
Priming Volume for CADD® High Volume Administration Sets (with Flow Stop Free-Flow Protection)	16 mL	16 mL	Same
Priming Volume for CADD® High Volume Administration Sets (with Air-Eliminating Filter and Flow Stop Free-Flow Protection)	23 mL	23 mL	Same
0.2 micron filter, for CADD® High	0.2 micron filter	0.2 micron filter	Same

Characteristic	Subject Device K172592	Predicate Device K031361	Discussion
Volume Administration Sets (with Air-Eliminating Filter and Flow Stop Free-Flow Protection)			
PVC Tubing Plasticized with TOTM	Yes	Yes	Same
Bag Spike	Yes	Yes	Same
Dimensions – Bag Spike	Same	Same	Same
Materials – Bag Spike	**Acrylonitrile butadiene styrene (ABS) – ABS - HI 121H-Natural Granule 9700640000 Colorant: Yellow**	**Acrylonitrile butadiene styrene (ABS) – ABS White Granule 9700670300 Colorant: White**	**Proposed materials are color-coded yellow to indicate medication intended for regional anesthetic delivery.**
Male Taper with One-Way Checkvalve	Male NRFit™ connector	Male ISO 594 Luer	**The NRFit™ connector provides the same clinical function (i.e., secure, non-leaking connection), but incorporates the ISO 80369-6 connector design to mitigate the risk of misconnections.**
Materials – One-Way Checkvalve, Valve Membrane	Silicone – Siloprene LSR-4040 Colorant: None	Silicone– Siloprene LSR-4040 Colorant: None	Same
Materials – One-Way Checkvalve, Male Taper Outlet Housing	Polycarbonate – Makrolon RX-1805G Colorant: Yellow, Clariant NC1M664867	Polycarbonate – Makrolon RX-1805G Colorant: Purple Tint	**Proposed materials are color-coded yellow to indicate medication intended for regional anesthetic delivery.**
Materials – One-Way Checkvalve, Female Luer Lock Inlet Housing	Polycarbonate – Makrolon RX-1805-013771 Colorant: White	Polycarbonate – Makrolon RX-1805-013771 Colorant: White	Same
Flow Stop	Yes	Yes	Same
Packaging	Pouch	Pouch	Same

7. SUMMARY OF NON-CLINICAL TESTING

The CADD® Yellow High Volume Administration Set with NRFit™ connector was evaluated via non-clinical performance testing to demonstrate the devices are as safe, as effective, and performs as well as the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the CADD® Yellow High Volume Administration Set with NRFit™ connector device performed as intended. A summary of the testing is provided in **Table 2**.

Table 2: Testing Type by Category

Category	Testing
Biocompatibility	Cytotoxicity Sensitization Intracutaneous Reactivity (Irritation) Acute Systemic Toxicity Pyrogenicity (bacterial-mediated & material-mediated) Hemocompatibility Subchronic Toxicity Genotoxicity Extractables and Leachables Toxicological Risk Assessment Particulates Ethylene Oxide Residuals
Packaging	Sterile Barrier Integrity Seal Strength Packaging Stability Distribution Simulation
Device Performance	Connector compatibility and incompatibility Dimensional Testing Leakage Mechanical Requirements (resistance to cracking, tensile strength, over-riding threads, torque)

Biocompatibility and Bench testing was conducted to the Standards in **Table 3**:

Table 3: Testing Type by Standard Reference Number and Date

Standards Development Organization	Reference Number and Date	Title
ISO	80369-1:2010	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
ISO	80369-6:2016	Small bore connectors for liquids and gases in healthcare Applications – Part 6: Connectors for Neuraxial Applications
ISO	10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO	10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO	10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO	10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO	10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO	10993-10:2010	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization
ISO	10993-11:2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO	10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO	10993-17:2002(R)2012	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO	10993-18:2005	Biological evaluation of medical devices – Part 18: Chemical characterization of materials

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The evaluation of the Smiths Medical CADD® Yellow High Volume Administration Set with NRFit™ connector device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate devices in regards to safety and effectiveness.