DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 20, 2017

Smiths Medical ASD, Inc.
Michael Johnson
Sr. Manager, Regulatory Affairs
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K162219
Trade/Device Name: CADD® Infusion Disposables Portfolio with NRFit™ connectors
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA, LHI
Dated: June 15, 2017
Received: June 19, 2017

Dear Mr. Michael Johnson:

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,

Tara A. Ryan -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K162219

Device Name
CADD® Infusion Disposables Portfolio with NRFit™ connector

Indications for Use *(Describe)*

CADD Yellow Medication Cassette Reservoirs with NRFit™ connector
CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors are designed for use only with NRFit™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility) and CADD Yellow Extension Sets with NRFit™ connectors.

CADD Filling Adapter with male NRFit™ connector and female Luer
The CADD Filling Adapter with male NRFit™ connector and female Luer is an accessory for use in filling of the CADD Medication Cassette Reservoirs with NRFit™ Connector.

CADD Yellow Extension Sets with NRFit™ connector
CADD Yellow Extension Sets with NRFit™ connectors are designed for use only with CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors for the delivery of regional anesthetics or narcotics.

CADD Yellow Administration Sets with NRFit™ connector
CADD Yellow Administration Sets with NRFit™ connectors are designed for use only with NRFit™ components for delivery of regional anesthetics or narcotics and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility).

Male Yellow Cap with NRFit™ connector
The Male Yellow Cap with NRFit™ connector is intended for use as an accessory with the CADD Yellow Medication Cassette reservoirs.

Female Yellow Cap with NRFit™ connector
The Female Yellow Cap with NRFit™ connector is intended for use as an accessory with the CADD Yellow Extension sets with NRFit™ connectors and the CADD Yellow Administration sets with NRFit™ connector.

CADD Infusion Adapter with male NRFit™ connector and female Luer
The CADD Infusion Adapter with male NRFit™ connector and female Luer is intended to be used by clinicians to convert administration sets with Luer connectors into permanently dedicated lines for use only with NRFit connectors. The NRFit™ connector with non-luer taper is intended for the injection or infusion of regional anesthetics or narcotics and may help reduce the risk of mis-connection or mis-injection.

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)	K162219
Applicant's Name and Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Michael R. Johnson Sr. Regulatory Specialist Phone: 763-383-3341 Fax: 763-383-3679 Email: mike.johnson@smiths-medical.com
Date	July 15, 2017
Regulation No.	21 CFR 880.5440
Regulation Name	Intravascular administration set
Primary Product Code	FPA
Secondary Product Code	LHI
Trade Name	CADD® Infusion Disposables Portfolio with NRFit™ connectors

2. REASON FOR SUBMISSION

The purpose of this submission is to make a modification to the currently marketed Smiths Medical CADD Yellow Infusion components which are being updated to include an ISO 80369-6 compliant connector for neuraxial applications.

3. DEVICE INFORMATION

	Subject Device	**Predicate Device**
Trade Name	CADD Yellow Medication Cassette Reservoir with NRFit™ connector	CADD Medication Cassette Reservoir
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	FPA
510(k)	K162219	K040636 (100ml), K081156 (250ml)
	Subject Device	**Predicate Device**
Trade Name	CADD Filling Adapter with NRFit™ connector	CorrectInject™ Safety System Infusion Adapter Component: The Infusion Adapter is a component of the CorrectInject Safety System which can be considered a transfer device or accessory to a syringe.
Regulation No.	21 CFR 880.5440	21 CFR 868.5140
Regulation Name	Intravascular administration set	Anesthesia Conduction Kit
Regulatory Class	II	II
Product Code	LHI	CAZ
510(k)	K162219	K110053

	Subject Device	**Predicate Device**
Trade Name	CADD Infusion Adapter with male NRFit™ connector and female Luer	CADD Administration Set with Flow Stop, Medication cassette reservoir with flow stop and extension set
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	FPA
510(k)	K162219	K040636
	Subject Device	Predicate Device
Trade Name	CADD Yellow Extension Set with NRFit™ connectors	Pharmacia Deltec, Extension Set with Anti-Siphon Valve
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	FPA
510(k)	K162219	K942046
	Subject Device	Predicate Device
Trade Name	CADD Yellow Extension Set with NRFit™ connectors and Air-Eliminating Filter	Extension Set with Microbore Tubing and Filter
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	FPA
510(k)	K162219	K974013
	Subject Device	Predicate Device
Trade Name	CADD Yellow Administration Sets with NRFit™ connector	CADD Administration Set
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	FPA
510(k)	K162219	K040636
	Subject Device	Predicate Device
Trade Name	Yellow Cap with NRFit™ connector	CADD Medication Cassette Reservoir
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	FPA
510(k)	K162219	K040636

4. DEVICE DESCRIPTION

The CADD® Infusion devices with NRFit™ connectors are part of the CADD System. The CADD System is defined as a CADD pump with an attached CADD Medication Cassette Reservoir with an integral free-flow protection feature and CADD Extension Set with an Integral Anti-Siphon Valve; or as a CADD pump with an attached CADD Administration Set with an integral free-flow protection feature. The CADD Administration Set will be connected to a medication bag to allow for infusion.

The devices are designed to deliver local or regional anesthetics, narcotics indicated for neuraxial or regional anesthetic infusion applications. 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 neuraxial or regional anesthetic use.

The CADD Infusion devices with NRFit ™ connectors are color-coded yellow to indicate medication intended for neuraxial or regional anesthetic delivery.

This 510(k) includes various configurations of CADD Infusion devices with NRFit ™ connectors. A description of each configuration is provided in the table below.

Configuration	Description
CADD Yellow Medication Cassette Reservoirs with NRFit™ connector	Self-contained, proprietary medication cassette reservoirs for use only with NRFit ™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps. Available in 100ml or 250ml.
CADD Filling Adapter with male NRFit™ connector and female Luer	An accessory used to fill the CADD Medication Cassette Reservoirs with NRFit ™ connectors.
CADD Infusion Adapter with male NRFit™ connector and female Luer	Used to convert administration sets or extension sets with Luer connectors into permanently dedicated line for use only with NRFit ™ connectors.
CADD Yellow Extension Sets with NRFit™ connector	Used only with CADD Yellow Medication Cassette Reservoirs with NRFit ™ connectors for the delivery of regional anesthetics or narcotics. Used to extend the distance between pump and patient. The extension set is configured with or without an air-eliminating filter.
CADD Yellow Administration Sets with NRFit™ connector	Dedicated administration set for use only with NRFit ™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps. The Yellow Administration sets are configured with or without an air-eliminating filter.
Male Yellow Cap with NRFit™ connector/ Female Yellow Cap with NRFit™ connector	The cap has an NRFit ™ thread design and is sold individually as an accessory that can be used to cap the Medication Cassette or Administration Set. The cap is available as a male yellow cap intended to fit the female NRFit ™ side or female yellow cap intended to fit the male NRFit™ side.

5. INDICATIONS FOR USE

Configuration	Indication for Use
CADD Yellow Medication Cassette Reservoirs with NRFit™ connector	CADD Yellow Medication Cassette Reservoirs with NRFit ™ connectors are designed for use only with NRFit ™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility) and CADD Yellow Extension Sets with NRFit™ connectors.
CADD Filling Adapter with male NRFit™ connector and female Luer	CADD Filling Adapter with male NRFit ™ connector and female Luer is an accessory for use in filling of the CADD Medication Cassette Reservoirs with NRFit ™ connector.

Configuration	Indication for Use
CADD Infusion Adapter with male NRFit™ connector and female Luer	The CADD Infusion Adapter with male NRFit ™ connector and female Luer is intended to be used by clinicians to convert administration sets with Luer connectors into permanently dedicated lines for use only with NRFit ™ connectors. The NRFit™ connector with non-Luer taper is intended for the injection or infusion of regional anesthetics or narcotics and may help reduce the risk of mis-connection or mis-injection.
CADD Yellow Extension Sets with NRFit™ connector	CADD Yellow Extension Sets with NRFit ™ connectors are designed for use only with CADD Yellow Medication Cassette Reservoirs with NRFit ™ connectors for the delivery of regional anesthetics or narcotics.
CADD Yellow Administration Sets with NRFit™ connector	CADD Yellow Administration Sets with NRFit ™ connectors are designed for use only with NRFit ™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD® pumps (see CADD pump Operator's Manual for compatibility).
Male Yellow Cap with NRFit™ connector/ Female Yellow Cap with NRFit™ connector	The Male Yellow Cap with NRFit ™ connector is intended for use as an accessory with the CADD Yellow Medication Reservoirs.
	The Female Yellow Cap with NRFit ™ connector is intended for use as an accessory with the CADD Yellow Extension sets with NRFit ™ connectors and the CADD Yellow Administration sets with NRFit ™ connector.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Smiths Medical CADD Infusion Disposables Portfolio with NRFit ™ connectors have the same technological characteristics as the predicate devices with the exception of the NRFit ™ Connectors.

The Smiths Medical CADD Infusion Disposables Portfolio with NRFit ™ connectors and predicate devices are both designed to deliver local or regional anesthetics, narcotics indicated for neuraxial or 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.

A comparative analysis is provided in the following Tables;

Table 1: CADD Yellow Medication Cassette Reservoir, 100mL with NRFit ™ connector

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette Reservoir with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids. The CADD administration Set with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids.	CADD Yellow Medication Cassette Reservoirs with NRFit ™ connectors are designed for use only with NRFit ™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility) and CADD Yellow Extension Sets with NRFit™ connectors.	Similar
Extension Set Length	8 inches	Same	N/A
Priming Volume	0.2 mL	Same	N/A

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Female Connector; Polyvinyl chloride (PVC) Male Connector; Polypropylene Housing; Polypropylene	Female Connector; Polycarbonate Male Connector; Polybutylene terephthalate (PBT) Housing; Polypropylene	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 2: CADD Yellow Medication Cassette Reservoir, 250mL with NRFit™ connector

Characteristic	Predicate (K081156)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette reservoirs are intended for the delivery of medications and fluids for subcutaneous, intramuscular, intravenous, intra-arterial, intraperitoneal, or intraspinal infusion.	CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors are designed for use only with NRFit™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility) and CADD Yellow Extension Sets with NRFit™ connectors.	Similar
Extension Set Length	8 inches	Same	N/A
Priming Volume	0.2 mL	Same	N/A
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections
Materials	Female Connector; Polyvinyl chloride (PVC) Male Connector; Polypropylene Housing; Polypropylene	Female Connector; Polycarbonate Male Connector; Polybutylene terephthalate (PBT) Housing; Polypropylene	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 3: CADD Filling Adapter with male NRFit™ connector and female Luer

Characteristic	Predicate (K110053)	Subject (K162219)	Discussion
Indication for Use	The CorrectInject™ Safety System is intended for the injection of local or regional anesthetics, narcotics or other medications indicated for neuraxial injection. The system consists of components that have a unique non-Luer taper that allows connection of compatible CorrectInject™ components that, when used together as a system, help reduce the risk of mis-connection that may result in the injection of medications not intended for neuraxial use.	CADD Filling Adapter with male NRFit™ connector and female Luer is an accessory for use in filling of the CADD Medication Cassette Reservoirs with NRFit™ connector.	Similar. The predicate Infusion Adapter is a component of the CorrectInject Safety System which can be considered a transfer device or accessory to a syringe. The subject Filling Adapter is an accessory used to fill the CADD Medical Cassette Reservoir and is considered a transfer device.
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Polybutylene terephthalate (PBT)	Polycarbonate – Bayer Polycarbonate Makrolon; Acrylonitrile butadiene styrene (ABS) – Terlux Colorant: Orange, Clariant and Clariant	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 4: CADD Infusion Adapter with male NRFit™ connector and female Luer

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette Reservoir with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids. The CADD administration Set with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids.	The CADD Infusion Adapter with male NRFit™ connector and female Luer is intended to be used by clinicians to convert administration sets with Luer connectors into permanently dedicated lines for use only with NRFit™ connectors. The NRFit™ connector with non-Luer taper is intended for the injection or infusion of regional anesthetics or narcotics and may help reduce the risk of misconnection or misinjection.	Similar

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Polybutylene terephthalate (PBT)	Polybutylene Terephthalate (PBT) Arnite; Polypropylene Polycarbonate (PC)	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Form Fill Seal	Form Fill Seal packaging is an appropriate alternative to the pouch packaging configuration.
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 5: CADD Yellow Extension Set with NRFit™ connectors

Characteristic	Predicate (K942046)	Subject (K162219)	Discussion
Indication for Use	The Extension Set with Anti-Siphon Valve is an accessory for use with administration sets that are used in conjunction with electromechanical infusion pumps that do not have anti-siphon valves. It is intended to protect against unregulated gravity infusion ("free-flow") from improperly attached administration sets.	CADD Yellow Extension Sets with NRFit™ connectors are designed for use only with CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors for the delivery of regional anesthetics or narcotics.	Similar
Set Length	90 inches	Same	N/A
Priming Volume	2.4 mL	Same	N/A
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Connectors; Polycarbonate Anti-Siphon Valve; Silicone-Elastosil	Connectors; Polycarbonate Anti-Siphon Valve; Silicone-Elastosil	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 6: CADD Yellow Extension Set with NRFit™ connectors and Air-Eliminating Filter

Characteristic	Predicate (K974013)	Subject (K162219)	Discussion
Indication for Use	The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for use with the CADD-Micropump. The Extension Set with Anti-Siphon Valve must be used with the Medication Cassette reservoir to protect against unregulated gravity infusion that can result from an improperly attached reservoir.	CADD Yellow Extension Sets with NRFit™ connectors are designed for use only with CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors for the delivery of regional anesthetics or narcotics.	Similar
Set Length	90 inches	Same	N/A
Priming Volume	2.4 mL	Same	N/A
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Female Connector; Polyvinyl chloride (PVC) Male Connector; Acrylonitrile butadiene styrene (ABS) Housing and Valve; Polycarbonate, Valve Membrane; Elastosil	Female Connector; Polycarbonate Male Connector; Acrylonitrile butadiene styrene (ABS) Housing and Valve; Polycarbonate, Valve Membrane; Elastosil	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 7: CADD Yellow Administration Sets

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette Reservoir with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids. The CADD administration Set with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids.	CADD Yellow Administration Sets with NRFit™ connectors are designed for use only with NRFit™ components for delivery of regional anesthetics or narcotics, and are designed for use with CADD pumps (see CADD pump Operator's Manual for compatibility).	Similar
Set Length (nominal)	123 – 130 inches	Same	N/A
Priming Volume	3.2 - 6.2 mL	Same	N/A

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Flow Type	Flowstop	Same	N/A
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit ™ connector intended to reduce risk of misconnections.
Materials	Bag Spike; Acrylonitrile butadiene styrene Valve; Siloprene, Housing; Polycarbonate	Bag Spike; Acrylonitrile butadiene styrene Valve; Siloprene, Housing; Polycarbonate	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Tyvek Pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 8: Male Yellow Cap with NRFit ™ connector

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette Reservoir with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids. The CADD administration Set with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids.	The Male Yellow Cap with NRFit ™ connector is intended for use as an accessory with the CADD Yellow Medication Cassette reservoirs.	Similar. The Cap is part of the CADD Medication Cassette Reservoir system.
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit ™ connector intended to reduce risk of misconnections.
Materials	Polybutylene Terephthalate	Polybutylene Terephthalate	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Form Fill Seal	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

Table 9: Female Yellow Cap with NRFit™ connector

Characteristic	Predicate (K040636)	Subject (K162219)	Discussion
Indication for Use	The CADD Medication Cassette Reservoir with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids. The CADD administration Set with Flow Stop is designed for use with the CADD pumps (except CADD-Micro and CADD-TPN) for delivery of medications and fluids.	The Female Yellow Cap with NRFit™ connector is intended for use as an accessory with the CADD Yellow Extension Sets with NRFit™ connectors and the CADD Yellow Administration sets with NRFit™ connector.	Similar. The Cap is part of the CADD Extension set and Administration sets.
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections.
Materials	Acrylonitrile Butadiene Styrene	Polybutylene Terephthalate	Subject device materials meet functional and biocompatibility requirements. Yellow indicates neuraxial or regional anesthetic application.
Packaging	Form Fill Seal	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A

7. SUMMARY OF NON-CLINICAL TESTING

The CADD Infusion Disposables Portfolio with NRFit™ connectors 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 CADD Infusion Disposables Portfolio with NRFit™ connectors performed as intended. A summary of the evaluation is provided below.

Category	Evaluation	Test Criteria
Functional Performance	Resistance to overriding	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Resistance to separation from axial load	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Resistance to separation from unscrewing	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Separation force of fitting assembly	ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
	Unscrewing torque of fitting assembly	ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
	Ease of assembly	ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
	Resistance to overriding	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Air Leakage	ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
	Liquid Leakage	ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
	Leakage by Pressure Decay	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Subatmospheric Pressure Stress Cracking	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Verifying Non-interconnectable characteristics physical force	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
Packaging	Package integrity, sterile barrier	ISO 11607, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
Sterilization	Sterility	ISO 11135, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.
	Residuals	ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
Biocompatibility	Intracutaneous	ISO 10993-10, Biological evaluation of medical devices -

Category	Evaluation	Test Criteria
	Toxicity	Part 10: Tests for irritation and skin sensitization
	Systemic Toxicity	ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	Sensitization	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
	Cytotoxicity	ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	Genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
	Leachable substances	ISO 10993-17, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances.
	Chemical characterization of materials	ISO 10993-18, Biological evaluation of medical devices - Part 18: Chemical characterization of materials
	Bacterial endotoxins	ANSI/AAMI ST72, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
	Particulate matter	USP 788, Particulate Matter in Injections

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The evaluation of the Smiths Medical CADD® Infusion Disposables Portfolio with NRFit™ connectors device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate devices in regards to safety and effectiveness. Device testing met pre-defined acceptance criteria and did not raise new question of safety or effectiveness.