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SECTION 5, 510(k) Summary

K110053

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Dr
Keene, NH 03431
(603) 352-3812, prompt 4, ext x2493
Contact: Cynthia Engelhardt
Regulatory Affairs Specialist
Summary Prepared: August 20, 2012

SEP 14 2012

Product Name:

Trade Name: CorrectInject™ Safety System
Common Name: Anesthesia Conduction Kit
Classification Name: Anesthesia Conduction Kit, (21 CFR 868.5140, Product Code CAZ)

Predicate Device(s):

K965017, Smiths Medical ASD, Inc. Portex® Regional Anesthesia Kits
K092657, EpiFuse™ Catheter Connector
K083451, Portex® Epidural Filter, Model 100/386/010, Various Standard and Custom Trays
K980987, BD Luer-Lok™ Tip Syringe
K801343, BD Nokor™ Filter Needle

Device Description

The CorrectInject™ Safety System specially designed non-Luer taper aids in preventing a standard Luer taper device from connecting or delivering a medication by the wrong route of administration.
The objective of the CorrectInject™ Taper system is to provide a non-Luer style, safety connection system that will help reduce the risk of misconnection.

The CorrectInject™ Taper system is intended to connect and be used solely with the components of the CorrectInject™ Safety System. The CorrectInject™ Safety System is intended to deliver medication to epidural and neuraxial locations.
CorrectInject™ Safety System components are considered **not** to be effectively connected if any of the following apply:

- Attachment to Luer components that requires the use of excessive force, torque, time or manipulation
- Physical resistance to attachment to Luer components beyond that defined in ISO 594-1, ISO 594-2 and BS EN 1707

- If an attachment is made to a standard Luer component, this attachment is non-functional as indicated by leakage per ISO 594-2, section 4.2 and BS EN 1707 section 4.2

The term "effectively connected" is defined as the ability to assemble linearly with normal clinical assembly force, or securely assemble together CorrectInject™ Safety System components using equivalent force, torque and technique, and resulting in a physically secure and functional assembly as defined by ISO 594 or BS EN 1707. The term "attachment" means to assemble such components that results in an assembly that may, or may not, be physically secure but is not functional as defined by ISO 594-1, ISO 594-2 and BS EN 1707.

The CorrectInject™ Safety System is designed to function in a similar manner as currently available Luer epidural systems. The locking components are attached together with a twisting motion the same as current Luer lock connectors. The difference in this system is that the interconnection taper is not a standard Luer taper (per ISO 594 Parts 1 &2).
This CorrectInject™ Safety System is color-coded yellow for a neuraxial system.

The design consists of several unique pieces:

1) Epidural Catheter Connector

The connector is identical to the Luer version of the EpiFuse® connector with the only differences being the taper is a non-Luer CorrectInject™ Taper, the cap is yellow not white and the word CorrectInject® is molded in the connector and printed in blue.

2) CorrectInject™ Syringe

The CorrectInject™ Safety System syringe is the same as a standard Luer syringe with the difference being a non-Luer CorrectInject™ Taper molded in place of a standard Luer taper. The CorrectInject™ Safety System syringe is available in 3ml, 5ml, 10ml and 20ml sizes.

3) Filter

The filter is identical to the Luer version of the filter with the only difference being the taper is a non-Luer CorrectInject™ Taper and the rotating collar is yellow and has a non-Luer CorrectInject™ fitting.

4) Filter Needle Assembly

The filter needle is the same as the standard Luer filter needle currently offered by Smiths Medical with an adaptor permanently attached to the Luer providing a non-Luer CorrectInject™ Safety System taper to allow connection to the CorrectInject™ Safety System syringe.

5) Caps

A yellow cap designed to fit the non-standard female side of the catheter connector or filter.

A white transport cap designed to fit the non-standard male side of a CorrectInject™ Safety System syringe.

6) CorrectInject™ non-Luer epidural label to identify the catheter and system as a non-Luer system.

Indications for Use:

CorrectInject™ Safety System

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.

CorrectInject™ Catheter Connector

The CorrectInject™ Catheter Connector is intended for use with an epidural anesthesia catheter and CorrectInject™ compatible components for the injection of local or regional anesthetics, narcotics or other medications indicated for injection into the epidural space.

CorrectInject™ Syringe

The CorrectInject™ Syringe is intended for use with CorrectInject™ compatible components for the injection of medications.

CorrectInject™ Filter

The CorrectInject™ anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid when used with CorrectInject™ compatible components.

CorrectInject™ Filter Needle

The CorrectInject™ filter needle is intended to draw up medication when using the CorrectInject™ Syringe.

CorrectInject™ White Transport Cap

The CorrectInject™ white transport cap is intended to fit the CorrectInject™ syringe.

CorrectInject™ Yellow Cap

The CorrectInject™ yellow cap is intended to fit the female side of the CorrectInject™ catheter connector or CorrectInject™ filter.

Technological Characteristics:

The proposed and predicate devices employ similar technology, i.e. the proposed and the predicate devices are for the injection of local or regional anesthetics, narcotics or other medications indicated for neuraxial injection. The difference is that the proposed system is **not** a Luer taper, but a non-Luer taper that is intentionally designed to be incompatible with Luer tapers.

All statements and representations set forth herein regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the

context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).

Non-Clinical Data:

Non-clinical testing for the CorrectInject™ Safety System has been conducted including visual, performance, dimensional characteristics, biocompatibility, chemical characterization and drug-device stability and compatibility testing.

The CorrectInject™ Safety System meets the requirements of the stated sections of BS 6196:1989, Sterile Epidural Catheters and Introducer Needles for Single Use, Section D.3.3 Only (Strength of union between catheter and catheter connector); BS EN 1707:1997, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings; ISO 594-1, Conical fittings with a 6% (Luer) taper for syringes needles and certain other medical equipment – Part 1 General Requirements; ISO 594-2., Conical fittings with a 6% (Luer) taper for syringes needles and certain other medical equipment – Part 2 Lock Fittings and ISO 7886-1:1993(E), Sterile hypodermic syringes for single use – Part 1: Syringes for manual use with a modification for the taper.

Chemical characterization has been performed in accordance with ISO Biological evaluation of medical devices — Part 18: Chemical characterization of materials.

Drug-device stability and compatibility testing has been performed to evaluate the stability and compatibility between the components of the CorrectInject™ Safety System and 3 drugs that are representative of the anesthetics, analgesics and narcotics that will be used in a continuous anesthesia system for intermittent administration of local anesthesia. The drug stability and compatibility was determined based on the assays of the drug products before and after infusion. The differences between the average assay result of a sample run in triplicate, and the assay result from its corresponding control sample were within ± 5.0% thus meeting the pre-set acceptance criteria.

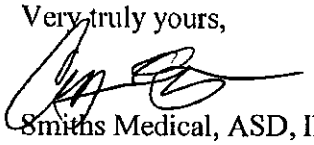
Clinical Data:

The clinical studies performed by Smiths Medical show that the system is safe and effective and will help reduce the risk of misconnections that lead to mis-injections of medication not intended for the epidural space. Most of the clinicians (85%) that participated in the study felt that the system is clinically acceptable.

Conclusion:

The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,



Smiths Medical, ASD, INC.
Cynthia Engelhardt
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2012

Smiths Medical ASD, Incorporated
Ms. Cynthia Engelhardt
Regulatory Affairs Specialist
10 Bowman Drive
Keene, New Hampshire 03431

Re: K110053
Trade/Device Name: CorrectInject™ Safety System, Catheter Connector, Filter, Infusio
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: September 7, 2012
Received: September 10, 2012

Dear Ms. Engelhardt:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K110053

Device Name: **CorrectInject™ Safety System**

Indications 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.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K110053

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): k 160 53

Device Name: **CorrectInject™ Catheter Connector**

Indications for Use:

The CorrectInject™ Catheter Connector is intended for use with an epidural anesthesia catheter and CorrectInject™ compatible components for the injection of local or regional anesthetics, narcotics or other medications indicated for injection into the epidural space.

Device Name: **CorrectInject™ Syringe**

Indications for Use:

The CorrectInject™ Syringe is intended for use with CorrectInject™ compatible components for the injection of medications.

Device Name: **CorrectInject™ Filter**

Indications for Use:

The CorrectInject™ anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid when used with CorrectInject™ compatible components.

Prescription Use (Part 21 CFR 801 Subpart D) _X_ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k 110053

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K110053

Device Name: **CorrectInject™ Filter Needle**

Indications for Use:

The CorrectInject™ filter needle is intended to draw up medication when using the CorrectInject™ Syringe.

Device Name: **CorrectInject™ White Transport Cap**

Indications for Use:

The CorrectInject™ white transport cap is intended to fit the CorrectInject™ syringe.

Device Name: **CorrectInject™ Yellow Cap**

Indications for Use:

The CorrectInject™ yellow cap is intended to fit the female side of the CorrectInject™ catheter connector or CorrectInject™ filter.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _3_ of _3__

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110053