K073188

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SECTION 5, 510(k) Summary

Smiths Medical ASD Inc.
Critical Care Division
10 Bowman Drive
Keene, NH 03431 0724, USA
T: +1 603 352 3812
F: +1 603 355 8157
www.smiths-medical.com

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812, prompt 4, ext 2493
Contact: Brian D. Farias
Regulatory Affairs Manager

Summary Prepared: November 9, 2007

Product Name:

Trade Name: **Hypodermic Needle-Pro® EDGE™ Safety Device**

Common Name:
Hypodermic Needle with attached needle protection.
Accessory to Blood Sampling Syringes.

Classification Name:
Hypodermic Single Lumen Needles (21 CFR 880.5570, Product Code FMI).
Accessory to Tubes, Vials, Systems, Serum Separators, Blood Collection (21 CFR 862.1675, Product Code JKA).

Predicate Device(s):

K071785 (Smiths Medical ASD, Inc.) Hypodermic Needle-Pro® EDGE™ Safety Device and EDGE™ Safety Device with Syringe

K911037 (Smiths Medical ASD, Inc.- formerly Concord/Portex) Safety Needle Sheath (modification)

Device Description:
This device is intended for injection or aspiration of fluids. The needle protection device covers the needle after use to help prevent needle sticks. The device features a "one-piece" design of needle hub and protective sheath with a living hinge. The needle cannula is permanently affixed into the hub. The sheath has an "arrow" indicating the bevel orientation, i.e. when the sheath is oriented to the right, the bevel is in the "up position". After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the lugs on the needle hub snap into the clips of the protective sheath resulting in a "bottom snap" and the needle is contained within the sheath. In addition to the "bottom snap", the needle protection sheath for needles equal to or less than 1" has one needle retaining hook (except 30g) and the sheath for needles longer than 1" has two hooks. The EDGE™ safety device may be removed from the syringe when required by a specific medical procedure. An example is removal of the EDGE™ safety device from a blood sampling syringe. The EDGE™ safety device is then discarded into a sharps container.

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Indications for Use:

Hypodermic Needle-Pro® EDGE™ Safety Device: This device is intended for injection or aspiration of fluids using a Luer lock or Luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks. The EDGE™ safety device may be removed from the syringe when required by a specific medical procedure.

Technological Characteristics:

The proposed and predicate devices all employ the same hinged style protective sheath that is manually activated after use.

Non-Clinical Data:
This abbreviated 510(k) submission declares conformance to the following standards:

ISO 594/1:1986(E), International Standard, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirements*

ISO 594-2:1998(E), International Standard, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2: Lock Fittings*

ISO 7864:1993(E), International Standard, *Sterile hypodermic needles for single use*

Clinical Data:
Simulated clinical use studies were conducted which confirmed that the EDGE™ safety device could be used by phlebotomists with no substantial change to their technique and could be safely removed from the syringe after activation.

Conclusion:
The bench testing and simulated clinical use studies demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Mr. Brian D. Farias
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K073188
Trade/Device Name: Hypodermic Needle-Pro® EDGE™ Safety Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 9, 2007
Received: November 13, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K073188

Device Name: **Hypodermic Needle-Pro® EDGE™ Safety Device**

Indications for Use:

This device is intended for injection or aspiration of fluids using a Luer lock or Luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks. The EDGE™ safety device may be removed from the syringe when required by a specific medical procedure.

Prescription Use X (Part 21 CFR 801 Subpart D) 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)

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

510(k) Number: K073188