K101180

AUG 3 - 2010

TAB 6

510(k) Summary

GRIPPER® Micro 1.25 Inch Needle

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510(k) Number:_____

Date Prepared April 23, 2010 Updated June 28, 2010

Submitter Information

Submitter's Name: Smiths Medical ASD, Inc.
Address: 1265 Grey Fox Road
St. Paul, MN 55112

Establishment Registration: 2183502

Contact Person: Rachelle Parsons, RAC
Sr. Regulatory Affairs Specialist

Phone: (651) 628-7018
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Device Information

Trade Name:	GRIPPER® Micro Blunt Cannula, Non-Coring Safety Needle; 1.25 inch
Common Name:	GRIPPER® Micro Needle
Classification Name:	Intravascular Administration Set
Product Code:	FPA
Regulation:	21 CFR §880.5440

Predicate Device(s)

The predicate devices are the currently marketed GRIPPER Micro Needles. The reference 510(k) number for these devices:

Device	510(k)
GRIPPER® Micro Blunt Cannula, Non-Coring Safety Needle	K072059

Device Description

The GRIPPER® Micro needle is comprised of the inserter and the infusion site with extension tubing and a standard luer fitting; there are versions either with or without needless access connector y-site. The inserter incorporates a sharp trocar needle and retractor arm. The infusion site incorporates a small septum and an attached blunt cannula. When fully assembled, the inserter and infusion site are combined with the trocar needle inserted through the septum and blunt cannula. After insertion of the cannula and trocar into the implanted port, the inserter retractor arm is activated removing the trocar needle from the cannula and infusion site septum leaving the blunt cannula in the implanted port. The trocar needle tip is captured in the inserter to prevent needle stick injury, and the inserter is discarded. Upon removal of the infusion site from the implanted port, the blunt cannula is designed to further prevent needle stick injury that may result from rebounding action during infusion site extraction.

Intended Use

The GRIPPER® Micro needle is designed for the administration into or withdrawal of fluids from implanted ports.

Indications for Use

The GRIPPER® Micro needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against accidental needlestick injuries.

Summary of Non-Clinical Testing

The non-clinical testing included assessment of the physical properties of the GRIPPER® Micro 1.25 inch needle and its ability to achieve its intended use. The GRIPPER Micro 1.25 inch products meet the same specifications as set for the predicate device. Testing performed based on FDA Guidance: *Guidance for Industry and FDA Staff – Medical Devices with Sharps Injury Prevention Features, August 2005* included force to attach and detach connections, force to activate and deactivate the safety features, rate of fluid flow simulating extremes of pressure and strength of joints and bonds. The Bench testing of the device confirmed the suitability of the device for its intended use.

Biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible based on the similarity of the materials of construction to the predicate devices commercially marketed by Smiths Medical ASD, Inc.

Summary of Clinical Testing

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the GRIPPER® Micro Needle. A Simulated Use Study was conducted according to the FDA Guidance: *Guidance for Industry and FDA Staff – Medical Devices with Sharps Injury Prevention Features, August 2005.* Health care professionals were selected to participate in the simulated use evaluation from a cross section of users or potential users of the device. These participants were experienced in accessing and de-accessing implantable portals.

The purpose of the study was to simulate actual clinical use of the GRIPPER Micro Needle System 1.25 inch by health care professionals, in terms of installation, activation of sharps protection and deaccess of the infusion site. The sample size was based on the statistical rationale noted in the FDA guidance. All 500 activations resulted in successful captures of the trocar tip in the capture zone.

Statement of Equivalence

The GRIPPER ® Micro 1.25 inch Needle is substantially equivalent to the currently marketed GRIPPER Micro Needles based on a comparison of the indications for use and the technological characteristics of the device.

Conclusion

The GRIPPER® Micro 1.25 inch Needle is substantially equivalent to the currently marketed GRIPPER Micro Needles based on the indications for use, technological characteristics, materials of construction and principles of operation of the device. Bench tests confirmed the suitability of the device for its intended use.

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

Ms. Rachelle Parsons
Senior Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

AUG 3 - 2010

Re: K101180
Trade/Device Name: GRIPPER® Micro Blunt Cannula Non- Coring Safety Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 2, 2010
Received: July 6, 2010

Dear Ms. Parsons:

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.

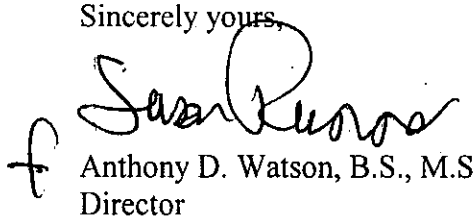
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

K101180

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification

GRIPPER® Micro Blunt Cannula Non-Coring Safety Needle
Indications for Use

AUG 3 - 2010

510(k) Number: **K101180**

Device Name: GRIPPER® Micro Blunt Cannula Non-Coring Safety Needle

Indications for Use:

This product is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against accidental needlestick injuries.

Prescription Use (Per 21 CFR 801 .109)	X	AND/OR	Over-The Counter Use (21 CFR 801 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: K101180