K102460

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SUMMIT MEDICAL PRODUCTS

JAN 13 2011

January 11, 2011

510(k) Summary

Device Sponsor:	Summit Medical Products, Inc. 2480 South Main Street Suite 212 Salt Lake City, UT 84115
Contact Information:	Marko Van Amen Summit Medical Products, Inc VP of Regulatory Affairs/Quality Assurance 2480 South Main Street Suite 212 Salt Lake City, UT 84115 Phone: 801-352-1888 FAX: 801-352-1818
Date Submitted	January 11, 2011
Trade Names:	ambIT Introducer, ambIT Sheath, ambIT Needle
Common Name:	Catheter Introducer
Classification Name:	Anesthesia, Conduction Catheter
Product Code:	BSO
Regulation Number:	868.5120
Equivalent To:	K063234 On-Q Introducers
Device Description:	The ambIT™ Introducer is intended for the percutaneous introduction of a catheter 1. A stainless steel shaft with a sharp tip. a. Stainless steel shafts with sharp tips (various configurations such as beveled or touhy) may or may not be solid (may be hollow).. The diameter of the stainless steel shaft ranges from 11 to 17 GA and the length is from 3.25 to 12 inches. 2. A plastic peelable sheath (split T-handle) on the outside of the stainless steel shaft and/or a plastic/metal inserts inside hollow stainless steel shafts. a. Introducers that have a plastic sheath will allow the catheter to be inserted after the stainless steel shaft has been withdrawn. The tips of the stainless steel shaft will be blunt or sharp. b. Introducers that do not have a plastic sheath will allow the catheter to be inserted through the stainless steel shaft, after the plastic/metal insert has been withdrawn. The ambIT Introducers may have a handle or luer hub connected to the stainless steel shaft.

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	The following are the configurations and names for the ambIT Introducers: 1. ambIT Introducer Sheath a. Sterile single use product b. Made for use with ambIT Tunneler (without sheath) reusable product. 2. ambIT Introducer Needle a. Sterile single use product b. Stainless steel shaft with sharp tip and insert inside stainless steel shaft.
Indications for Use:	The ambIT™ Introducer products are intended allow for the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle.
Substantial Equivalence (SE) Rational:	The ambIT™ Introducer product is considered substantially equivalent based on the materials that are used, the intended use, and both devices were tested to the same applicable ISO standards. The product passed all applicable testing requirements. The ambIT™ Introducer is intended for the percutaneous introduction of a catheter. In Section 2 of the 510(k) application for the ambIT Introducer device (K102460) a comparison of the proposed and predicate device is provided. A comparison of the proposed medical device, ambIT™ Introducer to the predicate medical device, the On-Q Introducer products (510K# K063234) is summarized below in **Table 1**. Both products have common features, such as they both use the similar materials of construction, similar intended use, and similar consensus standards for the design and performance for both devices

Table 1: Substantially Equivalence Comparison Table of proposed device –ambIT™ Introducer to the predicate device – ON-Q Introducer™.

Device	Proposed Device ambIT™ Introducer (510(k) #K102460)	Predicate Device On-Q Introducer (510(k) #K063234)
Intended Use	The ambIT™ Introducer products are intended allow for the percutaneous placement of catheters in close proximity to nerves and	The On-Q Introducers™ are intended for the percutaneous introduction and placement of

		around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle.	catheters into or around surgical wound sites and/or close proximity to nerves. Introducers with a luer hub may be used to aspirate or inject a bolus of fluid or medication prior to placing the catheters.
	Trade Names	ambIT Introducer, ambIT Needle, ambIT Sheath	ON-Q Needle, ON-Q Tunneler, ON-Q Sheath
	Materials of Construction	*Needle* • Stainless steel (304) needle 18 GA • Needle Hub- Polystyrene (clear)	*Needle* • Stainless steel (304) needle 18 GA • Needle Hub- Polystyrene (clear)
		Sheath • Tear away hub- High density Polyethylene (HDPE) • Sheath Shaft (tube)- High density Polyethylene (HDPE) with 10%BaSO4	*Sheath* • Tear away hub- High density Polyethylene (HDPE) • Sheath Shaft (tube)- High density Polyethylene (HDPE) with 10%BaSO4
		Tunneler Sheath • Sterile, single use product • Plastic peelable sheath	*Tunneler Sheath* • Sterile, single use product • Plastic peelable sheath

		Introducers • Sterile, single use product • Stainless steel shaft with a sharp end • Plastic peelable sheath	*Introducers* • Sterile, single use product • Stainless steel shaft with a sharp end • Plastic peelable sheath
Standards:	The ambIT Introducers meet the requirements as set forth in the following FDA recognized consensus standards for device design and performance requirements: • ISO 594-2 Liquid Leakage test • ISO 594-2 Air Leakage test • ISO 594-2 Separation Force test • ISO 594-2 Unscrewing Torque • ISO 594-2 Ease of Assembly • ISO 594-2 Resistance to Overriding • ISO 594-2 Stress Cracking • ISO 10555-1 Force to Break • ISO 10555-1 Strength of Union 1. ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing		
Safety and Effectiveness:	Based on the comparison to the predicate device and the conformance to the recognized standards, the ambIT Introducers are safe and effective and substantially equivalent to legally marketed devices.		

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

Mr. Marko Van Amen
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Summit Medical Products, Incorporated
2480 South Main Street
Salt Lake City, Utah 84115

JAN 13 2011

Re: K102460
Trade/Device Name: ambIT Introducers
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: August 28, 2010
Received: January 7, 2011

Dear Mr. Amen:

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

SUMMIT MEDICAL PRODUCTS

Abbreviated 510(k) – ambIT Introducer

510(k) Number K102460:

JAN 13 2011

Device Name: ambIT Introducers

Indications for Use:

The ambIT Introducer product line is intended to allow the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle

The ambIT Introducer product line is intended for use by a physician or by a trained individual under direct supervision of a physician.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) 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)

Richard C. Chapman 1/13/11

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

510(k) Number: K102460