K110814

APR - 8 2011

510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 807.92(c).

510(k) Number:	TBD
Owner Name:	Summit Medical Products, Inc.
Address:	2480 South Main Street #212 Salt Lake City, UT 84115
Contact Person:	Marko Van Amen VP of Regulatory Affairs/Quality Assurance Tel: 801.214.3464 Fax: 801.352.1888 Email address: mvanamen@summitmpi.com
Date Prepared:	January 23, 2011
Device Trade Name:	ambIT® Tunneler
Device Common Name:	Catheter Tunneler
Class:	Class II, 21 CFR 868.5120, Product Code BSO

Predicate Device(s):

- On-Q® Tunneler (K063234)

Device Description:

The ambIT® Tunneler is a non-sterile, reusable device indicated for use in the percutaneous introduction of catheters into and around the surgical wound site or close to the nerve. The ambIT® Tunneler is packaged and shipped non-sterile and must be cleaned and autoclaved by the purchaser/facility prior to use.

Summit Medical Products, Inc. is adding a tunneling device to the ambIT® Tunneler product line for use in the placement of catheters. This specification is specifically for a 16 gauge (GA), 12 inch shaft length, re-useable tunneler and single use sterilized peelable sheath.

The ambIT® Tunneler will consist of 2 components:

• The component is a stainless steel shaft (blunt end) with a handle. The diameter of the shaft is 16 GA (S French) and the length of the shaft will accommodate a 12 inch useable length sheath. The end of the shaft will have a rounded blunt tip.

Indication for Use:

The intended use is for the percutaneous introduction of catheters.

Comparison to Predicate Devices:

The proposed device, ambIT® Tunneler, covered under this 510(k) is similar to the predicate device, On-Q® Tunneler, with the exception of the predicate, On-Q® Tunneler, product's size offering. The On-Q® Tunneler shaft diameter ranges from 11 to 17 gauge and the length ranges from 3.25 to 12 inches. The ambIT® Tunneler has a shaft diameter of 16 GA and a length of 12 inches. The overall device component material is substantially equivalent; the tunnelers are made from a medical grade malleable stainless steel certified per ASTM 304. The proposed and predicate tunnelers are designed to have a blunt tip, as well as free from feathered edges, burrs and hooks.

Where minor technological differences exist between the proposed device and the predicate device, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

Summary of Non-Clinical Testing:

The proposed device, the ambIT® Tunneler, and the predicate device, the On-Q® Tunneler, met the requirements of the following FDA recognized consensus standards for the device design and performance requirements:

- ISO 10555-5:1996, Sterile, Single-Use Intravascular Catheters – Over Needle Peripheral Catheters
- ISO 9626:2001, Stainless Steel Needle Tubing
- ISO 17665-1:2006, Sterilization of health care products – Moist heat- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 9626:1991/amd 1:2001 Stainless steel needle tubing
- ISO 17664-2004 Sterilization of Medical devices

Results of testing demonstrate that the ambIT® Tunneler design meets product specifications and intended uses.

Statement of Equivalence:

The ambIT® Tunneler has the same indications for use and technological characteristics as the predicate device. Based on this and the design and engineering data provided in the Premarket Notification, the proposed ambIT® Tunneler has been shown to be substantially equivalent to the cleared On-Q® Tunneler.

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

Summit Medical Products, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

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Re: K110814
Trade/Device Name: ambIT Tunneler
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: March 22, 2011
Received: March 24, 2011

Dear Mr. Devine:

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.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: ambIT Tunneler

Indications For Use:

The ambIT Tunnelers are intended for the percutaneous introduction of catheters.

FDA CDRH DMC

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Prescription Use X (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)

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

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