JAN 17 2006

TOGO MEDIKIT CO., LTD.

17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City
Miyazaki Prefecture 883-0062, Japan

K052557

510(k) Summary per 21 CFR §807.92

Submitter's Name and Address	Togo Medikit Co. Ltd. 17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City Miyazaki Prefecture 883-0062 Japan
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Applicant	Heidi M. Erickson Specialist, Regulatory Affairs Phone: 763-694-3028 Fax: 763-694-6966 e-mail: ericksoh@bsci.com
Date Prepared	September 15, 2005
Proprietary Name(s)	Super Sheath Introducer Sheath
Common Name	Catheter Introducer
Product Code	DYB
Classification of Device	Class II, 21 CFR Part 870.1340
Predicate Device	Terumo Pinnacle Introducer Sheaths K954234 November 27, 1995

Device Description

The Super Sheath Introducer Sheaths are available in 4F-9F diameters and available in lengths ranging from 7 to 25 cm. Some sheaths may be ordered with a suture wing and some sheaths have radiopaque markers. The devices are provided sterile and are intended for one procedure use only.

The Medikit Super Sheath Introducer Sheath is packaged with a dilator. The Super Introducer Sheath Sets consists of a sheath, a dilator and a mini guidewire, with Inserter, as described in this submission or a US commercially available mini guidewire meeting Medikit specifications. The one-piece construction of the sheath shaft and hub allows smooth passage of medical devices. The sheath shaft and hub are made of polyamide and Ethylene Tetrafluoro ethylene ETFE (Teflon). Some sheaths have radiopaque markers that are embedded into the shaft 1.5 mm from the distal tip. The hubs, color-coded by French size, contain a hemostatic valve to prevent blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The sidetube extension is used for site management

The dilator is an open tapered plastic tube with an integral luer hub for guidewire insertion. It is inserted into the introducer sheath and facilitates and supports the entry of the sheath into the patient's vasculature. The dilator is longer than the sheath with a rounded tapered distal tip. . Once the sheath is in place the dilator is removed. There are two different dilators, 0.038" and a 0.035" guidewire compatible. The 4-8F-dilator tubes are made from Polypropylene (PP). The 9F dilator tubes are made of Fluorinated Ethylene Propylene (FEP). The dilator tubes are pressed into the dilator hub with a bushing. The sheath hub and the dilator hub lock using a rotating motion.

Super Sheaths can be ordered with a Polypropylene suture wing color coded by French size. The suture wing is a small projection near the hub with a hole in it for correct placement of the sheath using sutures.

Device Description continued

The uncoated mini guidewire is made of a stainless steel coil wrapped tightly around an inner mandrel that tapers at the distal tip. The flexible tip is J-shaped available in diameters of 0.035" and 0.038". The mini guidewire (with Inserter) is available in 45cm and 80cm lengths. The Inserter does not contact blood and is used strictly for guiding the guidewire into a cannula or introducer. A US commercially available mini guidewire (meeting Medikit specifications) may be used in the sets or the mini guidewire that is described in this submission.

Intended Use of Device

Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are intended for the introduction of diagnostic and interventional devices into the human vasculature.

Non-Clinical Test Summary

Functional testing for the Super Sheath consisted of sheath shaft tensile, sheath kink, sheath hub to shaft tensile, hemostatic valve integrity/sheath pressure, valve integrity of sheath, sheath lubricity, sheath radiopacity, and sheath/dilator corrosion resistance testing. Dilator functional testing consisted of dilator shaft tensile and dilator hub to shaft tensile testing. Mini Guidewire functional testing included tensile, combined load, torqueability, radiopacity and corrosion resistance. Biocompatibility, packaging and product shelf life testing has also been conducted. Test results verified that the Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are adequate for their intended use. Based on a comparison of intended use, design and the results of bench testing, Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets have been shown to be substantially equivalent to the predicate Terumo Pinnacle Introducer Sheaths (K954234) and are therefore deemed suitable for their intended use.

Technological Characteristics

The Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets and the Terumo Pinnacle Introducer Sheaths (K954234) are operated manually or by a manual process. The Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets use similar product design, packaging, sterilization methods and labeling when compared to Terumo Pinnacle Sheaths (the predicate device). The similar indications for use and technological characteristics support a determination of substantial equivalence. Differences in materials or manufacturing methods do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2006

Togo Medikit Co., Ltd.
c/o Boston Scientific Corporation
Ms. Heidi M. Erickson
Specialist, Regulatory Affairs
5905 Nathan Lane P-25
Plymouth, MN 55442

Re: K052557
Super Sheath Introducer Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: II
Product Code: DRE
Dated: December 27, 2005
Received: December 29, 2005

Dear Ms. Erickson:

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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Mahney

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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): K052557

Device Name: Super Sheath Introducer Sheath

Indications for Use: Introducer Sheaths and Introducer Sheath Sets are intended for use in the introduction of diagnostic and interventional devices into the human vasculature.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

10(k) Number K052557