APR 4 2006

K 060190

Section 7 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

7.1 General Provisions

Submitter's Name and Address	Togo Medikit Co. Ltd. 17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City Miyazaki Prefecture 883-0062 Japan
Contact Name and Information	Toshimitsu Hayashi Quality Assurance Manager Phone: 81-982-53-8027 Fax: 81-982-53-8008 e-mail: toshimitsu.hayashi@togomedikit.co.jp
Applicant	Heidi M. Erickson Specialist, Regulatory Affairs Phone: 763-694-3028 Fax: 763-694-6966 e-mail: ericksoh@bsci.com
Proprietary Name(s)	Super Sheath XL Introducer Sheath
Common Name	Catheter Introducer
Product Code	DYB
Classification of Device	Class II, 21 CFR Part 870.1340

7.2 Name of Predicate Device

Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets

7.3 Device Description

The Medikit Super Sheath Introducer XL Sheaths and Super Sheath XL Introducer Sheath Sets are similar to the 4-9F sheaths with the addition of four French sizes to the sheath line.

The Super Sheath XL Introducer Sheaths are available in 10F, 11F, 12F and 14F sizes and available in lengths ranging from 11 to 25 cm. The devices are provided sterile and are intended for one procedure use only.

The Medikit Super Sheath XL Introducer Sheath is packaged with a dilator. The Super Sheath Introducer XL Sheath Set consists of a sheath, a dilator and a mini guidewire, with inserter. The mini guidewires with inserter were cleared to market in K052557 (January 17, 2006). The construction of the sheath shaft and hub allows smooth passage of medical devices. The sheath shaft and hub are made of polyamide and fluorinated ethylene propylene FEP (Teflon). 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 side tube extension may be used for fluid and medication administration as well as blood sampling.

The dilator is an open tapered plastic tube with an integral luer hub for guidewire insertion. The guidewire 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. The dilators are 0.038" and a 0.035" guidewire compatible. The dilator tubes are made of fluorinated ethylene propylene (FEP). The dilator tubes are attached to the dilator hub using an epoxy resin. The sheath hub and the dilator hub lock using a rotating motion.

7.4 Intended Use

The Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature.

7.5 Summary of Technological Characteristics

The Medikit Super Sheath XL Introducer Sheaths and Super Sheath XL Introducer Sheath Sets are operated manually or by a manual process. The Medikit Super Sheath XL Introducer Sheaths and Super Sheath XL Introducer Sheath Sets use similar product design, packaging, sterilization methods and labeling when compared to the 4-9F sheaths (K052557). The similar indications for use and technological characteristics support a determination of substantial equivalence. Differences in materials do not raise any new issues of safety and effectiveness.

7.6 Non-clinical Test Summary

Testing was conducted to verify that the Super Sheath XL Introducer Sheaths met product specification. The following testing was performed:

- Sheath Shaft Tensile test
- Sheath Kink Test
- Sheath Hub to Shaft Tensile Test
- Hemostatic Valve Integrity/Sheath Pressure Test
- Sheath Valve Integrity/Sheath Pressure Test
- Dilator Shaft Tensile Test
- Dilator Hub to Shaft Tensile Test
- Real Time Product Shelf Lift Testing

Lubricity, radiopacity, sheath/dilator corrosion resistance testing, biocompatibility and package test reports were provided in K052557. The devices tested included the materials and packaging used in the devices included in this Special 510(k) notification. No new testing was conducted.

Test results verified that the Super Sheath XL Introducer Sheaths and Super Sheath XL Introducer Sheath Sets are adequate for their intended use. Based on a comparison of intended use, design and the results of bench testing, Medikit 10F, 11F, 12F, and 14F Super Sheath XL Introducer Sheaths and Super Sheath XL Introducer Sheath Sets have been shown to be substantially equivalent to the predicate (K052557) device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

TOGO Medikit Co., Ltd.
c/o Boston Scientific
5905 Nathan Lane
Mail Stop P-25
Plymouth, MN 55442
Attn: Ms. Heidi M. Erickson

Re: K060190
Super Sheath XL Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: March 15, 2006
Received: March 16, 2006

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 **Indications for Use**

K060190

Indications for Use

510(k) Number (if known): K060190

Device Name: Guide Sheaths and Guide Sheath Sets

Indications for Use: The Medikit Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
X		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmey

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060190