APR 5 2005

K050131

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510(k) Summary

InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe

(per 21CFR807.92)

1. SPONSOR

M.K. Meditech Co., Ltd.
18-38, No. 50, Sec. 1 Jhong Siao W. RD.
Taipei, 100
Taiwan, ROC

Contact Person: Kenny Chiang, QA Manager
Telephone: 02-23710558

Date Prepared: January 13, 2005

2. DEVICE NAME

Proprietary Name:	InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe
Common/Usual Name:	Insulin syringe
Classification Name:	Piston syringe Hypodermic single lumen needle

3. PREDICATE DEVICES

- 1 mL Bak'SNAP™ DuoProSS™ (K031594)
- Inviro Snap Safety Syringe (K040036)
- BD Safety-Glide (K992734)

4. DEVICE DESCRIPTION

The InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for syringe reuse. It is a sterile, single-use, with a pre-attached single lumen hypodermic needle. Syringe volumes include 1 mL, 0.5 mL, and 0.3 mL. Needles

range in size from 25G to 29G, with lengths of 3/8 inch to 1½ inches. The InsoSAFE™ is provided individually wrapped, in shelf boxes of 100 units.

5. INTENDED USE

The InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe intended for subcutaneous injection of insulin into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

M.K. Meditech Co., Ltd., makes a claim of substantial equivalence of the InsoSAFE™ Bak'SNAP™ to the cited predicates based on similarities in intended use, design, and technological and operational characteristics. The syringes are indicated for injecting insulin into the body, while helping to reduce the risk of sharps injuries. The InsoSAFE™ Bak'SNAP™ and cited predicate syringes have permanently attached, single-lumen hypodermic needles. All syringes are available in 1 mL volumes and the InsoSAFE and BD syringes are also available in 0.5 mL and 0.3 mL versions.

All syringes are provided sterile, single-use, and disposable. The InsoSAFE and the Inviro Snap syringes have two-part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. All syringes require the user to manually activate the safety mechanism. For the InsoSAFE and the Inviro Snap, this is done by retracting the needle-plunger into the syringe barrel, breaking off the plunger rod, and discarding the pieces. For the BD Safety-Glide, the user advances a protective sheath over the used needle. M.K. Meditech Co., Ltd., believes that the differences between the 1 mL DuoPro™ Safety Syringe and cited predicate devices are minor and they raise no new issues of safety or effectiveness.

7. TESTING

Verification and validation testing presented in this premarket notification includes testing to demonstrate conformance to standards and testing according to FDA guidance, "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Protection Features, December 2002."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

M.K. Meditech Company Limited
C/O Ms. Rosina Robinson, RN, MEd, RAC
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K050131
Trade/Device Name: M.K. Meditech Co., Ltd., InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: January 20, 2005
Received: January 21, 2005

Dear Ms. Robinson:

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) 276-0115. 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,

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

Enclosure

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510(k) Number (if known): K050131

Device Name: M.K. Meditech Co., Ltd.,
InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe

Indications For Use:

The InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe intended for subcutaneous injection of insulin into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

Prescription Use X (21 CFR 801 Subpart D) OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
...sion Sign-Off)
...vision of Anesthesiology, General Hospital,
...fection Control, Dental Devices

...(k) Number K050131