510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(k) submission guidance.

JAN - 3 2007

The assigned 510(k) number is: k062318

Submitter's Identifications:
Company: BIOTOP TECHNOLOGY CO., LTD.
Address: 12 F-2, No. 130, Chung-Hsiao E. Road, Sec.2, Taipei 100, Taiwan, R.O.C.
Contact person: Mark Lien

1. Name of the Device:
   HookSafe™ U-100 Insulin Syringe, models: 0.5cc/ml and 1cc/ml

2. Information of the 510(k) Cleared device (Predicate device):
   BIOTOP HookSafe™ Safety Syringe; models 0.5cc/mL, 1cc/mL, 3cc/mL, 5cc/mL, and 10cc/mL (k041970).

3. Device Description:
   The **HookSafe™ U-100 Insulin Syringe** is the Safety Syringe with the following functional advantage:
   <A> Single use, completely non-reusable, all parts and components can be safely discarded.
   <B> Fully meets anti-needlestick requirements and incorporates anti-reuse functionality. After the injection of insulin, it is at this stage where the anti-reuse function of our syringe begins, a mechanism within our syringe engages the needle hub and forms a lock. At this point, one simply needs to pull the syringe plunger back and the needle will be completely retracted into the barrel of the syringe. At this stage the syringe becomes completely harmless and fully meets its anti-reuse functionality.

4. Intended Use:
   The **HookSafe™ U-100 Insulin Syringe**; models 0.5cc/ml and 1cc/ml, serves as the vehicle in which medication, insulin can be injected into the human body, via the hypodermic needle injection. The safety mechanism may limit accidental needle stick injuries as well as help to prohibit syringe reuse.

5. Comparison to the 510(k) Cleared Device (Predicate Device):

   Since the new models **HookSafe™ U-100 Insulin Syringe**; model 0.5cc/ml and 1cc/ml, were developed from the cleared device HookSafe™ (1cc/ml) through the design control procedures of BIOTOP TECHNOLOGY CO., LTD. with only the small change in product name and scale graduation, the new device is substantial equivalence to that device being modified, HookSafe™ (1cc/ml) (K041970).

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

   Compliance to the applicable standards is completely identical to that of the device being modified, HookSafe™ (1cc/ml) (K041970).

7. Conclusions

   The BIOTOP **HookSafe™ U-100 Insulin Syringe**; model 0.5cc/ml and 1cc/ml have the same intended use and technological characteristics as the cleared device of BIOTOP'S model HookSafe™ (1cc/ml) (K041970). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2007

Ms. Lydia Lee
Regulatory Department Leader
BIOTOP Technology Company, Limited
Chung-Hsiao East Road, Sec. 2
12F-2, No. 130
Taipei, Taiwan 100

Re: K062318
Trade/Device Name: HookSafe™ U-100 Insulin Syringe; Models 0.5cc/ml and 1cc/ml.
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 25, 2006
Received: November 29, 2006

Dear Ms. Lee:

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.

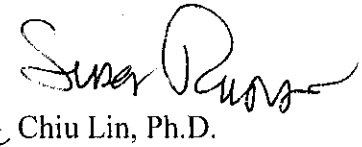
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications For Use

510(k) Number (if known):

Device Name: **HookSafe™ U-100 Insulin Syringe**; models 0.5cc/ml and 1cc/ml.

Indications For Use:

The **HookSafe™ U-100 Insulin Syringe**; models 0.5cc/ml and 1cc/ml, serves as the vehicle in which medication, insulin can be injected into the human body, via the hypodermic needle injection. The safety mechanism may limit accidental needle stick injuries as well as help to prohibit syringe reuse.

Prescription Use _____ OR Over-The-Counter Use ___√___

(Part 21 CFR 801 Subpart D) (21 CFR 807 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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