BIOTOP TECHNOLOGY CO., LTD.

K043038

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DEC 2 2 2004

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.

The assigned 510(k) number is: _____.

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:
   BIOTOP HookSafe™ LUER-LOCK Safety Syringe; models 3cc/mL, 5cc/mL, and 10cc/mL.

2. Information of the 510(k) Cleared Device (Predicate Device):
   BIOTOP HookSafe™ Safety Syringe; models 3cc/mL, 5cc/mL, and 10cc/mL (K041970).

3. Device Description:
   The HookSafe™ LUER-LOCK series is the Safety Syringe with the following functional advantage:
   <A> Single use, completely non-reusable, all parts and components can be safely inoperative and safely discarded.
   <B> Fully meets anti-needlestick requirements and incorporates anti-reuse functionality as well. As with any normal syringe, after the injection process, the syringe plunger should be fully depressed to ensure complete injection of the serum. It is at this stage where the anti-reuse function of our syringe begins; a mechanism within our syringe engages the syringe needle and forms a lock. At this point, one simply needs to pull the syringe plunger back again and the needle will be completely retracted into the barrel of the syringe. Because the needle, when retracted, is in a stably-tilted position and forced against the inner shoulder of the syringe barrel. At this stage the syringe becomes completely harmless and fully meets its anti-reuse functionality.

4. Intended Use:
   The BIOTOP HookSafe™ LUER-LOCK Safety Syringe; models: 3cc/mL, 5cc/mL, and 10cc/mL serves as the vehicle in which medication can be injected into the human body, or fluid withdrawn from the human body, via the hypodermic needle injection.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™ LUER-LOCK models: 3cc/mL, 5cc/mL, and 10cc/mL were developed from the cleared device HookSafe™ models: 0.5cc/mL, 1cc/mL, 3cc/mL, 5cc/mL, and 10cc/mL through the design control procedures of BIOTOP TECHNOLOGY CO., LTD. with only the small change in the needle change mechanism, the new device is substantial equivalence to that of device being modified, HookSafe™ models: 3cc/mL, 5cc/mL, and 10cc/mL.

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™ models: 3cc/mL, 5cc/mL, and 10cc/mL.

7. Conclusions

The BIOTOP HookSafe™ LUER-LOCK Safety Syringe; models 3cc/mL, 5cc/mL, and 10cc/mL have the same intended use except for the needle change mechanism and technological characteristics as the cleared device of BIOTOP's model HookSafe™ models: 3cc/mL, 5cc/mL, and 10cc/mL. 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

DEC 22 2004

Mr. Mark Lien
Official Correspondent
Biotop Technology Company Limited
12 F-2, No.130, Chung-Hsiao E. Road,
Sec.2, Taipei 100,
TAIWAN, R.O.C.

Re: K043038
Trade/Device Name: BIOTOP HookSafe LUER-LOCK Safety Syringe;
Models 3cc/mL, 5cc/mL, and 10cc/mL
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 7, 2004
Received: December 16, 2004

Dear Mr. Lien:

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.

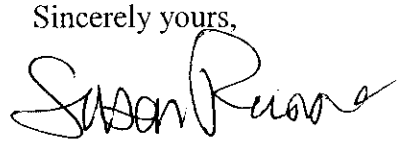
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K043038

Indications For Use

510(k) Number (if known):

Device Name: BIOTOP HookSafe™ LUER-LOCK Safety Syringe; models 3cc/mL, 5cc/mL, and 10cc/mL.

Indications For Use:

The BIOTOP HookSafe™ LUER-LOCK Safety Syringe; models 3cc/mL, 5cc/mL, and 10cc/mL serves as the vehicle in which medication can be injected into the human body, or fluid withdrawn from 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

510(k) Number K043038