

510(K) SUMMARY
OCT 21 2005

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: In6 IncuVestor® Inc.
Address: No. 413 Ming-Hsouie Rd., Taipei, Taiwan
Phone: 886-2-2532-2825
Fax: 886-2-2532-2822
Contact: Ms. Lin Lee, Lee / PRESIDENT

2. Device Name :
Trade Name: In6 IncuVestor® Inc.
Common Name: Safety Syringe (provided with needle)
Classification name Anti-Stick Syringe

3. Classification: Class II
Regulatory Number: 880.5860
Product Code: MEG

4. Predicate Device: • VANISHPOINT SYRINGE (K980069) marketed by
RETRACTABLE TECHNOLOGIES, INC.

5. Device Description: The **In6 Safety Syringe (3ml)** is sterile, single-use, disposable , Non-reusable, Retractable, Piston Syringe, provided with needle attached in place., which is intended for the injection of medication into a patient, while minimizing the potential for accidental injury as a result of needle-stick (sharps injury).

In6 Safety Syringe (3ml) works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. The needle retracting mechanism is activated by a spring action mechanism after injection is completed, while the exposed needle remains safely inside the empty syringe barrel for disposal.

The **In6 Safety Syringe (3ml)** consist of the following major components.

1. Plunger , 2. Barrel , 3. Piston, 4. O- Ring ,5. Spring, 6. Needle Hub,
7. U.V. Glue, 8. Cannula , 9. Needle Protector.

6. Intended Use: The **In6 Safety Syringe (3ml)** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe reuse and is a single use, disposable and retractable safety syringe which is intended for injection of medical fluids into the body.

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7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 7864, ISO 7886-1, ISO 10993 series, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions: The **In6 Safety Syringe (3ml)** has the same intended use and similar technological characteristics as the VANISHPOINT SYRINGE (K980069) marketed by RETRACTABLE TECHNOLOGIES, INC.. Moreover, bench testing & simulated use study contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **In6 Safety Syringe (3ml)** is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 21 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IN6 Incuvestor, Incorporated
C/O Ms. Jennifer Reich
Harvest Consulting Corporation
3892 South America West Trail
Flagstaff, Arizona 86001

Re: K051800
Trade/Device Name: IN6 SAFETY SYRINGE, MODEL 3ML
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: October 13, 2005
Received: October 17, 2005

Dear Ms. Reich:

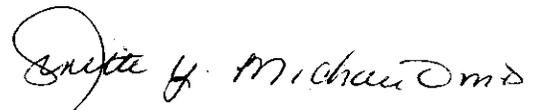
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K051800

DEVICE NAME: **In6 Safety Syringe (3ml)**
In6 IncuVestor® Inc.

INDICATIONS FOR USE:

The **In6 Safety Syringe (3ml)** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe reuse and is a single use, disposable and retractable safety syringe which is intended for injection of medical fluids into the body.

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 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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