K072654

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR PATIENT SAFE SYRINGE™
(21 CFR 807.92)

Contact Person: Rhonda Wells
Regulatory Affairs Manager

Date of Summary Preparation: September 18, 2007

DEC 1 4 2007

Trade Name: Patient Safe Syringe™
Common Name: Piston Syringe
Classification Name: Piston Syringe

Device Classification: Class II

Legally Marketed Substantially Equivalent Device:
Nipro Disposable Syringes (K030683)

Description of Device: The Patient Safe Syringe™ is a 3 piece piston syringe consisting of a calibrated hollow barrel and a movable plunger with a plunger seal. One end of the barrel has a male connector (nozzle) which permits attachment to a female (hub). The collar on the luer end is slightly extended to protect and prevent contact contamination of the luer tip and is compatible with most luer fittings.

Intended Use: The intended use of the Patient Safe Syringe™ is to aspirate fluid and inject fluids into the body. Additionally, the unique design of the syringe protects the luer tip from contact contamination prior to injection, thus reducing the risk of medication contamination and bloodstream infections resulting from luer tip contamination.

Comparison of Technical Characteristics:
The subject Patient Safe Syringe™ and the Nipro predicate device are very similar in design and technological characteristics and identical in materials.

Substantial Equivalence: The Patient Safe Syringe™ is different from the Nipro Disposable Syringe only in the design of the collar at the luer end of the syringe. The manual operation, similar design and identical materials between the predicate device and the subject device do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Ms. Rhonda Wells
Regulatory Affairs Manager
Retractable Technologies, Incorporated
511 Lobo Lane
Little Elm, Texas 75068-0009

Re: K072654
Trade/Device Name: Patient Safe Syringe™
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 19, 2007
Received: September 20, 2007

Dear Ms. Wells:

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

510(k) Number (if known): K072654

Device Name: Patient Safe Syringe™

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072654