

**PREMARKET NOTIFICATION**  
**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR**  
**PATIENT SAFE® LUER CAP**  
**(21 CFR 807.92)**

FEB 24 2011

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**Applicant Name:** Retractable Technologies, Inc.  
511 Lobo Lane  
Little Elm, TX 75068  
**Phone:** 972-294-1010  
**Contact Person:** Rhonda Wells  
Regulatory Affairs Manager

K101708

**Date of Summary Preparation:** February 14, 2011

**Trade Name:** Patient Safe® Luer Cap  
**Common Name:** Luer/ Tip Cap  
**Classification Name:** FMF – Piston Syringe  
**Device Classification:** Class II  
**Legally Marketed Substantially Equivalent Device:**

K801311 – Burrton Multi-AD Syringe Cap

**Description of Device:** The Patient Safe® Luer Cap is for use on luer tips of other devices to prevent leakage and contact and/or environment contamination during transport to patient area.

**Intended Use:** The intended use of the Patient Safe® Luer Cap is to cover male luer fittings (luer lock and luer slip), to reduce the risk of touch contamination and medication leakage.

**Engineering Testing:** Liquid leakage testing was performed in accordance with FDA Recognized Standard ISO 594-1. The Patient Safe® Luer Cap will reduce the risk of touch contamination and medication leakage.

**Simulated Use Study:** A simulated use study was conducted by Retractable Technologies, Inc, to ensure the Patient Safe® Luer Cap can effectively be used by the clinician while promoting aseptic technique. The subject device was attached to six (6) different types of luer tips. The Patient Safe® Luer Cap satisfied all requirements of the protocol to protect the luer tip from touch contamination, liquid leakage and ease of use.

**Comparison of Technical Characteristics:** The Patient Safe® Luer Cap and the predicate device are similar in design, technological characteristics and materials. Biocompatibility testing was performed on all materials with acceptable results. The subject luer cap has the same intended use as other luer/tip caps currently being marketed.

**Substantial Equivalence:** The manual operation, similar design and materials between the predicate device and the subject device do not raise new issues of safety and effectiveness. As an accessory device, the Patient Safe® Luer Cap is made of a material currently approved by the FDA and does not raise new issues of safety and effectiveness. It is our opinion that the devices are substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

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

FEB 24 2011

Re: K101708  
Trade/Device Name: Patient Safe® Luer Cap  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: FMF  
Dated: February 14, 2011  
Received: February 15, 2011

Dear Mr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

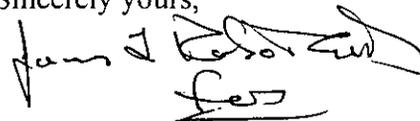
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
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 STATEMENT**

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510(k) Number (if known): K101708

Device Name: Patient Safe® Luer Cap

Indications for Use:

The intended use of the Patient Safe® Luer Cap is to cover male luer fittings (luer lock and luer slip), to reduce the risk of touch contamination and medication leakage.

Prescription Use   
(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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

R. C. Chapman 2/24/201

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

(Optional Format 3-10-98)

510(k) Number: K101708