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

FEB 24 2011

K101708

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

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 – Burron 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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 √ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)

(Optional Format 3-10-98)

RLC Chapman 2/24/201
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101708