FEB 18 2011

Section 5: 510(k) Summary

Assigned 510(k) number:	K101233
Company:	Rexam Healthcare 600 Deerfield Parkway Buffalo Grove, IL 60089 Phone: 317-346-5178 Fax: 317-736-9016
Contact:	Jeffrey Burris
Date Prepared:	March 23, 2010
Proprietary Names:	Safe'n'Sound Passive Delivery System
Classification Name:	Piston syringe accessory
Classification:	21 CFR 880.5860, Class II, Product Code MEG
Predicate Device:	K060743 UltraSafe® Passive Delivery System by Safety Syringes, Inc.
Device Description:	The Safe'n'Sound Passive Delivery System is an anti-needlestick accessory for use with sterile prefilled ISO Standard glass syringes. It fits 1 mL long staked needle

	syringes, and consists of a body assembly and a loose plunger rod.
Intended Use:	Single use devices that are indicated for use as an accessory with sterile 1 mL long staked needle prefilled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks. The devices can be used on a wide range of patients including children and adults.
Technological Characteristic Comparison Summary to Predicate Device:	The Safe'n'Sound Passive Delivery System is similar to the predicate device in general technological features and principle of operation. Both are molded plastic assemblies consisting of a body, sleeve, plunger rod, and spring that activates upon injection completion to fully contain the needle. Minor differences between the devices in technological features and performance have been demonstrated to be insignificant based upon bench testing and simulated clinical use studies performed.
Performance Testing:	Bench testing has been performed on the Safe'n'Sound Passive Delivery System. It confirmed the product functions as intended and is substantially equivalent to the predicate device. Biocompatibility testing has been performed demonstrating that the product meets ISO 10993-5 and ISO 10993-10 requirements.
Clinical Testing:	Simulated clinical use testing has been performed. It confirmed that the Safe'n'Sound Passive Delivery System could be used safely and effectively to shield needles inside the protection device after use.
Conclusion:	Based upon the design, technology, performance, functional testing, and intended use, the Safe'n'Sound Passive Delivery System is substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act. The Safe'n'Sound Passive Delivery System raises no new issues of safety or effectiveness.

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. Jeffrey Burris
Global Regulatory Affairs Manager
Rexam Pharma
600 Deerfield Parkway
Buffalo Grove, Illinois 60089

FEB 18 2011

Re: K101233
Trade/Device Name: Safe'n'Sound Passive Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe Accessory
Regulatory Class: II
Product Code: MEG
Dated: February 9, 2011
Received: February 11, 2011

Dear Mr. Burris:

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.

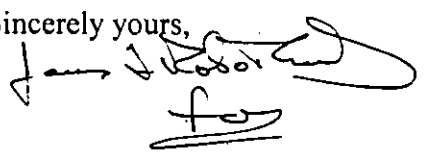
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

510(k) Number (if known): K101233

Device Name: Safe'n'Sound Passive Delivery System

Indications for Use:

Single use devices that are indicated for use as an accessory with sterile 1 mL long staked needle prefilled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks. The devices can be used on a wide range of patients including children and adults.

Prescription Use ___X____ AND/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)

2/18/11

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

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