K123743

510(k) SUMMARY

UltraSafe Passive PLUS Needle Guard

MAR 2 6 2013

Company: Safety Syringes, Inc.
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Contact Person: Suzanne Richardson
Vice President, Quality Assurance and Regulatory Affairs

Mary Stanners, RAC
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Date Prepared: December 5, 2012

Trade/Proprietary Name: UltraSafe PLUS Passive Needle Guard

Common Name: Anti Stick Syringe

Classification Name: Piston Syringe

Classification Number(s)/Product Code(s) : 21 CFR 880.5860 (MEG)

Legally Marketed Predicate Device: UltraSafe Passive Needle Guard (510(k) K011369, K060743, K122558)

Device Description:
The modification to the predicate device is the addition of the X100L PLUS device to the UltraSafe Passive Needle Guard X-Series family. The SSI UltraSafe PLUS Passive Needle Guard is an anti-needlestick accessory for pre-filled ISO standard glass syringes. The device is composed of a guard, body, spring and plunger, is non-sterile and single use. The activation of the UltraSafe PLUS Passive Needle Guard device remains the same. Upon completion of the injection, the guard will slide forward, cover and lock over the needle of the syringe. It is a visual and/or tactile and/or audible recognition that the device safety feature has activated. The SSI devices are categorized as skin contact with a duration of category A- limited (< 24 h) as per ISO 10993 *Biological evaluation of medical devices- Part 1: Evaluation and testing.*

Intended Use/ Indications for Use:
The intended use remains the same. It is a safety mechanism to reduce occurrence of accidental needle sticks when using ISO standard glass prefilled syringes.

The indications for use remain the same with additional claims. The UltraSafe Passive Needle Guard is indicated for use as single use devices that are indicated for use as an accessory with pre-filled 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 intended patient population is unrestricted and may include children and adults, and

parenteral methods of administration. Additionally, the PLUS device is designed with a larger viewing window indicated where pharma company offering is a low fill volume and instructions request visualization. The PLUS device is designed with a robust plunger and built in extended finger flanges indicated where pharma customer offering is viscous.

Technical Characteristics Comparison Summary to Predicate Device:
The UltraSafe PLUS Passive Needle Guard is substantially equivalent to the predicate device in general technological features and principle of operation. The mechanism of action of the device does not change. Upon completion of the injection, the syringe will retract and guard will lock over the needle of the syringe.

Performance Data:
Bench testing was performed on the UltraSafe PLUS Passive Needle Guard and confirms that the PLUS functioned as intended and is substantially equivalent to the predicate X-Series device. Safety Syringes, Inc. maintains a Quality System compliant with 21 CFR 820, *Quality System Regulation*. The firm's Quality System is registered by TUV SUD America to ISO 13485:2003, *Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes*. Test procedures, test protocols, and reports are maintained within the Quality System. The firm uses the standard elements of design control compliant to 21 CFR Part 820 and ISO 13485:2003 to develop its new products. Risk Management was conducted as per ISO 14971 *Medical device-Application of risk management to medical devices*. Biocompatibility testing performed demonstrates that the additional plungers met the requirements of Blue Book Memorandum G95-1 *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*.

Clinical Testing:
As per FDA guidance and ISO 23908: *Sharps Injury Protection-Requirements and Test Methods-Sharps Protection Features for Single-Use Hypodermic Needles, Introducers for Catheters and Needles Used for Blood Sampling*, simulated use studies were conducted on the PLUS device, testing 500 devices with zero failures for activation for a *"97.5% confident that the true failure rate was no higher than 0.7% and 99.5% confidence that it is no higher than 1.1%"*as per the FDA Guidance to ensure that the UltraSafe PLUS Passive Needle Guard did not impede or adversely affect the intended clinical performance of the device, did not activate prematurely under expected conditions of use and provided protection against unintended sharps injury until disposal. All injections were completed successfully; the safety device activated in all 500 devices with zero failures, consistent with the emptying of the syringe and administering all the medication, meaning the device did not impede the intended clinical performance. All 500 devices activated with zero failures meaning the device activated at the appropriate time under expected conditions of use and provided protection against unintended sharps injury until disposal. (Reference *Guidance for Industry and FDA: Medical Devices with Sharps Injury Prevention Features* and ISO 23908: *Sharps injury protection-Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*).

Conclusion:
Based upon the design, technology, performance and functional testing, the UltraSafe PLUS Passive Needle Guard device is substantially equivalent to predicate device previously cleared as 510(k)s K011369, K0607043 and K122558.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2013

Ms. Suzanne Richardson
Vice President, Quality Assurance and Regulatory Affairs
Safety Syringes, Incorporated
2875 Loker Avenue East
CARLSBAD CA 92010

Re: K123743
Trade/Device Name: UltraSafe PLUS Passive Needle Guard
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: February 12, 2013
Received: February 21, 2013

Dear Ms. Richardson:

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 -S
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): TBD K123743

Device Name: UltraSafe PLUS Passive Needle Guard

Indications for Use:

Single use devices that are indicated for use as an accessory with pre-filled 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 intended patient population is unrestricted and may include children and adults, and parenteral methods of administration. Additionally, the PLUS device is designed with a larger viewing window indicated where pharma company offering is a low fill volume and instructions request visualization. The PLUS device is designed with a robust plunger and built in extended finger flanges indicated where pharma customer offering is viscous.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123743