

K122SS8

## 510(k) SUMMARY

### UltraSafe Passive Needle Guard

SEP 20 2012

**Company:** Safety Syringes, Inc.  
2875 Loker Avenue East  
Carlsbad, CA 92010 USA  
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**Contact Person:** Suzanne Richardson  
Vice President, Quality Assurance and Regulatory Affairs  
  
Mary Stanners, RAC  
Senior Regulatory Specialist

**Date Prepared:** August 17, 2012

**Trade/Proprietary Name:** UltraSafe 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 Delivery System (510(k) K011369, K060743)

#### **Device Description:**

The SSI UltraSafe Passive Needle Guard (X-Series) 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 SSI UltraSafe 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 tactile and visual recognition that the device safety feature has activated. The modifications to the predicate device include additional plungers manufactured from Purell PolyOne X50109 polypropylene homopolymer, Ineos H20Z-00 polypropylene homopolymer or medical grade Delrin SC690 NC010. 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. 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.

**Technical Characteristics Comparison Summary to Predicate Device:**

The UltraSafe 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 guard will slide forward, cover and lock over the needle of the syringe.

**Performance Data:**

Bench testing was performed on the UltraSafe Passive Needle Guard and confirms that the additional plungers functioned as intended and are substantially equivalent to the predicate device. Safety Syringes, Inc. maintains a Quality System compliant with 21 CFR 820, *Quality System Regulation*. The firm's Quality System is registered by a third-party 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 10993 requirements.

**Clinical Testing:**

As per FDA guidance and ISO 23908, simulated use studies were conducted to ensure that the additional plungers 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 (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, functional testing and intended use, the UltraSafe Passive Needle Guard device is substantially equivalent to predicate device previously cleared as 510(k)s K011369 and K0607043.



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

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

SEP 20 2012

Re: K122558  
Trade/Device Name: UltraSafe Passive Needle Guard  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: MEG  
Dated: August 17, 2012  
Received: August 22, 2012

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

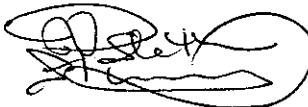
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding 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,

For 

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

INDICATIONS FOR USE

510(k) Number (if known): TBD

Device Name: UltraSafe 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.

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The Counter Use       

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number:   122 558