

K012121

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**(510k) Summary of Safety and Effectiveness**

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, Safety and Effectiveness information is enclosed for the following device:

**Device Name:** SECUREGARD® Retractable Safety Syringe  
**Trade Name:** SECUREGARD® Syringe  
**Common Name:** Safety Syringe  
**Classification name:** Piston Syringe / Anti-Stick Syringe

**Device Class:** Class II  
**Classification Code:** MEG

**Performance Standard:** None established.

**Safety and Effectiveness:** No new issues safety and effectiveness as relating to hypodermic syringes. The sharps injury prevention feature was demonstrated to be easily and safely activated by the user, and the needle was effectively shielded by the sharps protection feature.

**Facility Address:** SafeGard Medical Systems (Hungary) KFT  
Jozséréncsét tér 15, H-3608  
Farkaslyuk, Hungary

**Establishment Registration Number:** 9616482

**Indications for Use:** The intended function of the SECUREGARD® Retractable Safety Syringe is to provide a safe and reliable method of intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection. The SECUREGARD® Retractable Safety Syringe is also intended to prevent needle stick injuries. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

**Substantial Equivalence:** The SECUREGARD® Retractable Safety Syringe is substantially equivalent to the SOLOGARD® Locking Plus Syringe. The SECUREGARD is a sterile, single-use, disposable hypodermic syringe with sharps injury and reuse prevention features. It is manufactured in sizes of 0.5, 1, 2, 2.5, 3, 5, 10 and 20 mL volume.

**Contact Information:** Pat Grant Jr.  
Director Regulatory Affairs  
SafeGard Medical Products, Inc  
52 Dragon Court  
Woburn, MA 01801  
Tel. (781) 935 2275  
Fax (781) 935 8424



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SafeGard Medical Products, Incorporated  
C/O Mr. Mike Dayton  
BioMed Research, Incorporated  
14802 Hadleigh Way  
Tampa, Florida 33624

Re: K012121

Trade/Device Name: SECUREGARD® Retractable Safety Syringes  
Regulation Number: 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: MEG  
Dated: September 21, 2001  
Received: October 1, 2001

Dear Mr. Dayton:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

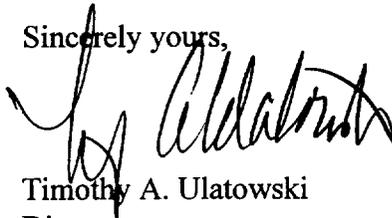
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

