MAR - 8 2000

K990831

SUPERGUARD™ SAFETY SYRINGE PREMARKET NOTIFICATION [510(K)] SUMMARY

Submitter's Name:	US Safety Syringes Co., Inc.
Address:	1290 East Oakland Park Boulevard, Suite 200 Fort Lauderdale, FL 33334-4447
Telephone:	954-561-9500
Fax:	954-561-8835
Contact Person:	James Ginesi, President
Date 510(k) Summary Prepared:	March 8, 1999
510(k) Number:	TBD
Trade or Proprietary Name(s):	*SuperGuard*™ Safety Syringe
Common Name:	Piston Syringe; Anti-stick Syringe
Classification Name:	Piston Syringe
Predicate Device(s):	Becton Dickinson Safety-Lok® Syringe (K920321 and K924072) Becton Dickinson Plastipak® (pre-amendment)
Device Description:	The *SuperGuard* ™ Safety Syringe is a piston syringe combined with a sharps Injury Prevention mechanism that shields the hypodermic needle from exposure and reuse after an initial use.
Intended Use:	The *SuperGuard*™ Safety Syringe is intended as a sterile, single use, disposable syringe for use in the administration of intramuscular injection.

Summary of Technological Characteristics to Predicate Device:	The *SuperGuard* ™ Safety Syringe is an anti-stick device that retracts the needle into a protective sleeve after use and prevents reuse. All component materials are identical to the named predicate devices and, therefore, the *SuperGuard* ™ Safety Syringe is substantially equivalent.

— End of Premarket Notification [510(k)] Summary —

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2000

Mr. James Ginesi
President
U.S. Safety Syringes Company, Inc.
1290 East Oakland Park Boulevard
Suite 200
Fort Lauderdale, Florida 33334-4447

Re: K990831
Trade Name: SuperGuard™ Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 12, 1999
Received: January 5, 2000

Dear Mr. Ginesi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

7. Revised Indications for Use

510(k) Number (if known): K990831

Device Name: **SuperGuard™ Safety Syringe**

Indications For Use:

The *SuperGuard*™ Safety Syringe is intended as a sterile, single use, disposable syringe, employing an antistick device, for use in the administration of intramuscular and subcutaneous injections.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990831

(Optional Format 1-2-96)