K972878

UltraSafe® Injection System
510(k) Premarket Notification
Models B50, B100, B100L, B150, B225 and B300
Needle Guard

OCT 30 1997

9.0 Summary of Safety and Effectiveness

9.1 Safety Syringes Contact Person

David Mitchell
Safety Syringes, Inc.
250 West Colorado Blvd.
Suite # 101
Arcadia, CA 91007
(626) 821.1121 Phone
(626) 821.1009 Fax

9.2 Device Name

UltraSafe® Injection System Needle Guard

9.3 Predicate Devices

Safety Syringes UltraSafe® Aspirating Syringe - K944425

9.4 Product Description and Function

The UltraSafe® Needle Guard is an accessory to the ISO 11040-4 standard glass syringe that is pre-filled. The device is totally disposable. It is a safety guard that can be mated with a pre-filled syringe of the same size. After use of the syringe, the guard is activated covering the needle and thus protecting the caregiver by eliminating the need to recap the needle and minimizing accidental needle stick injuries during disposal of the syringe/needle.

9.5 Comparison to Predicate Devices/Equivalence

Descriptive Comparison to Legally Marketed Devices
The Needle Guard requires a two-handed action in order to cover the needle point after use.

The Needle Guards have been tested and found to have considerably greater strength than the predicate device. The Guard is easy to assemble and use with a prefilled syringe.

With the Needle Guards in the "ready-to-use" position, they provide the same useable needle length as an unguarded needle. The user can perform typical hypodermic procedures equivalently to standard, unguarded needles.

9.6 Comparison of Materials

The UltraSafe® Injection System Needle Guards are made of K-Resin KR03 and KR01, which are the same materials as the Safety Syringes predicate device.

9.7 Safety and Efficacy Information

Biocompatibility:
The UltraSafe® Injection System uses the same material as the Safety Syringes predicate device. The material has passed biocompatibility tests.

Labeled Warning Statements:
Hands must remain behind the needle at all times during use and disposal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

Mr. Anthony R. Perez
CEO & President
Safety Syringes, Incorporated
250 W. Colorado Boulevard, Suite 101
Arcadia, California 91007

Re: K972878
Trade Name: Ultrasafe® Injection System Needle Guard, Models B50,B100,B100L,B150,B225 & B300
Regulatory Class: II
Product Code: FMF
Dated: July 31, 1997
Received: August 4, 1997

Dear Mr. Perez:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 obligation you might have under sections 531 through 542 of 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) 594-4618. 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" (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

510(k) Number (if known): K972878

Device Name: UltraSafe® Injection System Needle Guard Models B50, B100, B100L, B150, B225 & B300

Indications For Use:

Each UltraSafe® Injection System Needle Guard is attached to an ISO standard glass syringe that is pre-filled and equipped with a shield that covers the needle during disposal intending to reduce the occurrence of accidental needle sticks to users. This device is used for a wide range of patients from children to adults and parenteral methods of administration.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K972878

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

(Optional Format 1-2-96)