

FEB 26 1998

**UltraSafe® Injection System
Model T200 Injector with Needle Guard
510(k) Premarket Notification**

K 97290 0

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, Model T200 Injector with Needle Guard

9.3 Predicate Devices

Safety Syringes UltraSafe® Aspirating Syringe - K944425
Wyeth TUBEX® Injector - Pre-amendment

9.4 Product Description and Function

The UltraSafe® Model T200 Injector with Needle Guard is a product which is intended to be used with a TUBEX® Sterile Cartridge-Needle Units 2.5 ml to deliver medication from the cartridge into the tissues of the patient. The device is totally disposable and is equipped with a needle shield which can be snapped into place after use of a syringe, 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
Model T200 Injector with Needle Guard is intended to be used to deliver medication from a cartridge. The guard

requires a two-handed action in order to cover the needle point after use.

The Model T200 Injector with Needle Guard has been tested and found to have considerably greater strength than the predicate device. The T200 Injector is as easy to assemble and use as the Wyeth Injector.

With the Model T200 in the "ready-to-use" position, it provides 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, Model T200 Injector with Needle Guard is made of K-Resin KR01, KR03, and ABS Resin which are the same materials as the Safety Syringes predicate device.

9.7 Safety and Efficacy Information

Biocompatibility:

The UltraSafe® Injection System, Model T200 Injector uses the same materials as the Safety Syringes predicate device. The materials have passed biocompatibility tests.

Labeled Warning Statements:

Hands must remain behind the needle at all times during use and disposal.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K972900
Trade Name: UltraSafe® Injection System Model T200
Injector with Needle Guard
Regulatory Class: II
Product Code: FMF
Dated: January 6, 1998
Received: January 7, 1998

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.

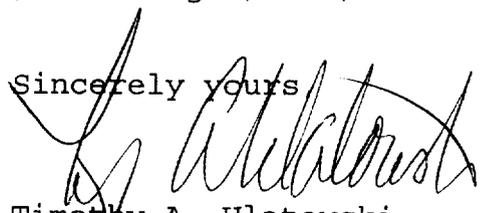
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K972900

Device Name: UltraSafe® Injection System Model T200 Injector With Needle Guard

Indications For Use:

The UltraSafe® Model T200 Injector with Needle Guard is designed to hold a TUBEX® Sterile Cartridge-Needle Unit 2.5 ml. in place while administering an injection. The guard is intended to protect the user from needle sticks after injection and during disposal of the needle cartridge unit.

The UltraSafe® Model T200 Injector is used with a Tubex® Sterile Cartridge-Needle Unit 2.5 ml. to deliver medication from the cartridge to the tissue of a patient, and is equipped with a shield that covers the needle during disposal. This device is used for a wide range of patients from children to adults and for parenteral methods of administration.

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

Palacios Consent
Concurrence of CDRL Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K972900
Prescription Use
(Per. 21 CFR 801.109)

Over-The-Counter Use

OR

(Optional Format 1-2-96)