MAY 21 1999

K991039

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
[21 CFR 807.92]

510(k) Number:	Pending
Proprietary Name:	EasySafe™ Retracting Needle Syringe
Common Name:	Retracting Needle Syringe
Manufacturer:	Saf-T-Med, Inc. 1250 South Grove, Suite 200 Barrington, IL 60010
Predicate Device Information:	A claim of substantial equivalence is made to: USMI SafeSnap™ Syringe, K925039 BD syringe (pre-Ammendment device)
Device Claims:	For the injection of fluid intramuscularly (IM) into the body, while helping to reduce the risk of sharps injuries and reducing the amount of wasted medication.

In compliance with the requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification.

Effectiveness

In two recent simulated use studies, over 1,500 injections/fluid withdrawals were administered by a wide variety of clinicians to test the effectiveness of the product in injecting fluids into or withdrawing fluids from a patient. All injections/withdrawals were successfully completed.

Bench testing of the product confirms its compliance with the applicable performance standards established by the International Standards Organization (ISO).

In focus groups twenty clinicians indicated that they saw no impediments to being able to effectively administer injections to patients using the product.

Safety

In two recent simulated use studies, over 1,500 injections/fluid withdrawals were administered by a wide variety of clinicians to test the safety of the product when used to inject fluids into or withdraw fluids from a patient. No injuries of any kind were reported.

Bench testing of the product confirms its comparability with legally-marketed predicate devices for a variety of safety factors, including but not limited to graduation accuracy and needle guard puncture resistance.

Biocompatability testing was performed by outside contract laboratories, with the results indicating that, from a biocompatability standpoint, the product is safe for its intended purpose.

A variety of design factors are intended to improve upon patient and clinician safety during use of the product. While sample size requirements have precluded a broad statistical study of the impact of such factors on injury rates, clinicians have reacted in a unanimous fashion to those factors.

A detailed risk analysis was performed on the product and, based on information currently available, the risk of harm from the product appears to be relatively low.

Sterilization validation was conducted by an outside contract laboratory. Sterilization to a SAL of 10^{-6} was confirmed during the tests. Pyrogenicity was also evaluated and acceptable results obtained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1999

Mr. James Erbs
President
Saf-T-Med, Incorporated
1250 South Grove, Suite 200
Barrington, Illinois 60010

Re: K991039
Trade Name: EasySafe® Retracting Needle Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 25, 1999
Received: March 29, 1999

Dear Mr. Erbs:

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 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) 594-4692. 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,

Susan Runner

FX 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):_____

Device Name: EasySafe® Retracting Needle Syringe

Indications For Use:

The primary intended use of the EasySafe® Retracting Needle Syringe is to inject fluid into, or withdraw fluid from the body. The secondary intended uses are:

1. to help prevent sharps injuries when using the product for its primary intended use, and;
2. to help reduce wasted medication when using the product for its primary intended use.

(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)

(Optional Format 1-2-96)

Paloma Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971037