K013801

DEC 1 3 2001

510(k) Summary

Special 510(k) summary of safety and effectiveness

Company Information
Safety Syringes, Inc.
1939 Palomar Oaks Way, Suite A
Carlsbad, CA 92009

Device Information
Trade Name – UltraSafe Dental™ Injection System – Model TBD
Classification Name – Syringe, Antistick
Classification – Class II
Product Code – 80 MEG

Predicate Device
UltraSafe Aspirating Syringe

Device Description
The UltraSafe Dental™ Injection System is a sterile, single use Needle Guard assembly to help prevent needlestick and a reusable Syringe Plunger assembly that is used to administer local anesthetic solutions.

Intended Use
Purpose and Function

The UltraSafe Dental™ Injection System is intended for use by dental healthcare professionals for injecting anesthetic into oral tissues with a syringe that provides a needlestick prevention mechanism. The anti-needlestick feature of this syringe system may be activated in between injections and at the conclusion of injections. When the Needle Guard is activated, it provides added protection to the dental healthcare professional from an accidental needlestick.

At the conclusion of injections, the dental healthcare professional disposes of the used syringe into a sharps disposal container.

Intended Patient Population

The intended patient population is unrestricted and includes children and adults of all ages.

Intended Environment of Use

The intended environment of use is where dental healthcare professionals inject anesthetic into oral tissues by means of a syringe system (e.g., dental offices, dental clinics, oral surgery).

Indications for Use

The UltraSafe Dental™ Injection System is a sterile, single use Needle Guard assembly and a reusable Syringe Plunger assembly that is indicated for use with pre-filled, 1.8mL, anesthetic cartridges for injection of anesthetic solution for profound anesthesia of oral tissues.

The Needle Guard sheath manually slides forward over the needle in between injections and after injection(s) have been completed. The Needle Guard helps protect dental healthcare professionals from accidental needlesticks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Ms. Thomas L. Hall
Director, Regulatory Affairs & Quality Assurance
Safety Syringes, Incorporated
1939 Palomar Oaks Way, Suite A
Carlsbad, California 92009

Re: K013801
Trade/Device Name: UltraSafe Dental Injection System
Regulation Number: 880.5860
Regulation Name: Syringe, Antistick
Regulatory Class: II
Product Code: MEG
Dated: November 15, 2001
Received: November 15, 2001

Dear Mr. Hall :

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) 594-4613 . 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

K013801

Indications for Use Statement

510(k) Number (if known): _____

Device Name: UltraSafe Dental™ Injection System
(Syringe, Antistick)

Indications for Use:

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The Needle Guard sheath manually slides forward over the needle in between injections and after injection(s) have been completed. The Needle Guard helps protect dental healthcare professionals from accidental needlesticks.

The intended patient population is unrestricted and includes children and adults of all ages.

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

_____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over the Counter_____
(Per 21 CFR 801.109

Susan Runner

(Division Sign-Off)
Division of Dental Infection Control,
and General Hospital Devices
510(k) Number K013801