SEP 3 0 2003

K032247

510(k) Summary
for the
U.S. Technologies, Inc. Retractable Safety Syringe

(per 21CFR807.92)

1. SPONSOR

U.S. Technologies, Inc.
1512 West Chester Pike, #122
West Chester, PA 19382

Contact Person: Mr. Abrar Solatch, President
Telephone: 610-659-9833

Date Prepared: July 15, 2003

2. DEVICE NAME

Proprietary Name:	U.S. Technologies, Inc., Retractable Safety Syringe
Common/Usual Name:	Hypodermic Syringe (with detachable needle)
Classification Name:	Piston syringe
	Hypodermic single lumen needle

3. PREDICATE DEVICE

- E.N.S.I. Retractable Safety Syringe (K003348, K000572)

4. DEVICE DESCRIPTION

The U.S. Technologies, Inc., Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable 5 mL safety syringe, provided with a detachable 22 gauge, 1¼ inch needle.

5. INTENDED USE

The U.S. Technologies, Inc., Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe which is intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

U.S. Technologies, Inc., makes a claim of substantial equivalence of the U.S. Technologies, Inc., Retractable Safety Syringe to the E.N.S.I. Retractable Safety Syringe (K003348, K000572) based on similarities in intended use, design, technological, and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce the risk of sharps injuries. Both syringes are piston syringes that use single lumen hypodermic needles. The U.S. Technologies, Inc., Retractable Safety Syringe is provided with a 22 gauge, 1¼ inch hypodermic needle, while the E.N.S.I. is not provided with needles. Both the U.S. Technologies, Inc., Retractable Safety Syringe and the E.N.S.I. products use a Luer lock connector. Both syringes are provided sterile, single-use, and disposable. Both the U.S. Technologies, Inc., Retractable Safety Syringe and the E.N.S.I. product are supplied with a volume of 5 mL.

Bench testing shows that the operation and performance of the U.S. Technologies, Inc., Retractable Safety Syringe is equivalent to the E.N.S.I. product. Both syringes have two-part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. Both syringes require the user to manually retract the needle/plunger into the syringe barrel, break off the plunger rod, and discard the pieces.

U.S. Technologies, Inc., believes that the differences between the U.S. Technologies, Inc., Retractable Safety Syringe and the predicate device are minor and raise no new issues of safety or effectiveness.

7. PERFORMANCE TESTING

Testing provided in this premarket notification includes biocompatibility, measurement of latex protein, packaging integrity, standards conformity, and testing according to FDA guidance (including a simulated use test).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2003

Medical Device Consultants, Incorporated
Ms. Rosina Robinson
Senior Staff Consultant
U.S. Technologies, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032247
Trade/Device Name: U.S. Technologies, Incorporated Retractable Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 12, 2003
Received: September 15, 2003

Dear Ms. Robinson:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032247

Device Name: U.S. Technologies, Inc. Retractable Safety Syringe

Indications For Use:

The U.S. Technologies, Inc., Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety piston syringe which is intended for injection of fluids into the body while reducing the risk of a sharps injury and potential reuse of the syringe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032247

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

(Optional Format 1-2-96)