SEP 2 3 2005 K051762

## SECTION 5: 510(k) RELEASABLE SUMMARY

### 510(k) Summary
(As Required by 21 section 807.92 (c))

1. **Submitter Name:** Safety Medical International, Incorporated
2. **Address:** 2055 Sprint Blvd
   Apopka, FL 32703
3. **Phone:** (407) 880-2301
4. **Fax:** (407) 880-3357
5. **Contact Person:** David L. Zarrilli, Chief Executive Officer
6. **Date Summary Prepared:** June 29, 2005
7. **Device Trade or Proprietary Name:** Saf-T-Syringe
8. **Device Common or usual name:** Retractable Needle Safety Syringe
9. **Device Classification Name:** Piston Syringe, AntiStick, with Hypodermic Needle
10. **Substantial Equivalency is claimed against the following devices:**

POP-N-LOCK SYRINGE ( currently marketed as the VANISHPOINT™ SYRINGE) from RETRACTABLE TECHNOLOGIES, INC., 510k #k946219, BD INTEGRA™ Syringe, from BECTON DICKINSON MEDICAL SURGICAL, 510(k) #k011103.

**11. Description of the Device:**
The Saf-T-Syringe is a 3cc, 5cc, and 10cc, sterile, non-toxic, non-pyrogenic, disposable, one-hand operated, passively activated, automatic retraction, plunger type, Anti-Stick syringe with a unique, dedicated luer-lock hypodermic needle, as detailed within this submission and in relevant patents. The syringe includes an interchangeable needle; 18 gauge to 25 gauge and lengths of 5/8", 1" and 1-1/2".

The primary intended use of the device is to administer safe and accurate subcutaneous and intramuscular injections. Its secondary intended use is to retract and contain the contaminated needle after injection which renders the syringe inoperable for reuse, while not introducing any additional steps to the one-handed operating method, for the purpose of aiding in the prevention of accidental needle stick injuries.

**12. Intended Use of the Device:**
The Saf-T-Syringe's primary intended use is to provide a safe, accurate and reliable method of injecting medication into a patient. The syringe is available in a 3cc, 5cc and 10cc with various needle sizes. Because the contaminated needle automatically withdraws into the needle plunger the syringe is protected from accidental needle sticks

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**13. Safety and Effectiveness of the Device:**
This device is safe and effective as the predicated devices cited above

The Saf-T-Syringe is sterilized using the Ethylene Oxide Sterilization method. The sterility of the device is assured using this sterilization method, which is validated in accordance with ANSI/AAMI/ISO 11135-1994, "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization" and BS EN 1174; Parts 1-3(1996-1997) "Sterilization of Medical Devices – Part 1: Estimation of the Population of Microorganisms on Product: Requirements; Part 2: Guidance; and Part 3: Guide to the Methods for Validation of Microbiological Techniques." The Saf-T-Syringe is sterilized to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

The Saf-T-Syringe is classified as an Externally Communicating Device, Blood Path Indirect, Limited Use (< 24 hours). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): "Use of International Standard ISO 10993 – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and ISO 10993: Parts 1, 4(AMD1), 5, 10, 11 (1993-2004) "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; Part 4 (AMD 1): Selection of Tests for Interaction with Blood; Part 5: Test for In Vitro Cytotoxicity; Part 10: Tests for Irritation and Delayed Type Hypersensitivity; and Part 11: Tests for Systemic Toxicity. Results of the testing demonstrate that the blood contacting materials are biocompatible.

**14. Summary Comparing Technological Characteristics With Predicate Devices:**
Safety Medical International, Incorporated makes a Substantial Equivalence claim of the Saf-T-Syringe to Retractable Technologies, Inc., Pop-n-Lock Syringe (currently marketed as the Vanishpoint™ syringe), 510(k) #k946219, and to Becton Dickinson's Spring-based Syringe (currently marketed as the Integra™ syringe) 510(k) #011103. All three syringes are similar, and in some cases the same, with regards to parts, design, material, operating procedure, and intended use. The Saf-T-Syringe, the VanishPoint™, and the Integra™, all consist of a syringe barrel, syringe plunger, single lumen hypodermic needle and needle hub, and all have a retracting mechanism on the syringe plunger tip and the needle stem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2005

Mr. David L. Zarrilli
Chief Executive Officer
Safety Medical International, Inc.
2055 Sprint Boulevard.
Apopka, Florida 32703

Re: K051762
Trade/Device Name: SAF-T-SYRINGE/SAF-T-NEEDEL
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: June 29, 2005
Received: June 30, 2005

Dear Mr. Zarrilli:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 4: STATEMENT OF INDICATIONS OF USE

### INDICATIONS FOR USE

510(k) Number (if known): 051762

Device Name: Saf-T-Syringe

Indications for Use:

The Saf-T-Syringe's primary intended use is to provide a safe, accurate and reliable method of injecting medication into a patient. The syringe is available in a 3cc, 5cc and 10cc with various needle sizes. The needle automatically withdraws and prevents accidental needle sticks.

3cc, 5cc, and 10cc Syringes are available for:

Prescription Use ___X___ (Part 21 CFR 801, Subpart D) OR Over-the-Counter Use _____ (Part 21 CFR 801, Subpart C)

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

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Concurrance of CDRH. Office of Device Evaluation (ODE)

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

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