

JUN 20 2000



SAFETY MEDICAL SUPPLY INTERNATIONAL, INC.
 135 BEAVER STREET 4TH FLOOR WALTHAM, MA 02154 (781) 642-7171 FAX (781) 642-7373

“510 (k) Summary”
 as required by section 807.92 (c)

807.92(a) (1)

Submitter's Name: Yovette Mumford-President of Safety Medical Supply International, Inc.

135 Beaver Street 4th Floor

Waltham, MA 02452-8424

(781) 642-7171 Fax (781) 642-7373

Contact Name: Yovette Mumford or Geneva Burchell

Date Summary was prepared September 10, 1999

807.92 (a) (2)

Trade Name: **SafetyTip™ Multi-Sample Needle**

Common Name: Blood Collection Needle

Classification Name: Needle, Hollow Double Lumen, All types;80 FMI
 Class II Device

Trade name: **SafetyTip™ Blood Collection System**

Common Name: Tube Holder

Classification Name: Tube Holder JKA Class II Device

807.92(a)(3)

The legally marketed devices to which Safety Medical Supply International, Inc. claims equivalence:

(For the SafetyTip™ Multi-Sample Needle)

Bio-Plexus “Punctur-Guard”

Sherwood “Monoject”

Becton Dickinson “Vacutainer”

(For the SafetyTip™ Blood Collection System)

Bio-Plexus “Standard Needle Holder”

Sage “Blood Needle Holder System”

Becton Dickinson “Safety-Lok Needle”

807.92(a)(4)

Description of the devices:

The Multi-Sample needle consists of a Cannula, Hub, Safety Sheath, Rubber Sleeve, and lower cover.

The Multi-Sample needle consists of a hypodermic needle in sizes 18 Gauge to 22 gauge with lengths of 1" to 3 ½". It has a hinged cover/sheath that is pulled open by the user by pinching the sides to expose the needle. When closing there are two levels, first. Close the sheath over the needle by pressing the needle down against any hard surface. At this point the needle may be re-opened by using the normal technique. To use the permanent locking system, close the sheath over the needle by pressing the needle down against any hard surface then, pressing the tip of the sheath with more force until the needle is lodged between the locking tabs, creating a permanent lock.

The SafetyTip™ Blood Collection System consists of a Cannula, Hub, Safety Sheath, Medical Surgical Grade Rubber Sleeve Holder and The Tube Holder. This is a "safety" device in that by using the permanent-locking feature, It may prevent accidental needlesticks. Its one-handed closing motion is in compliance with the CAL-OSHA standards. When closing the SafetyTip™ Blood Collection System there are two levels, first. close the sheath over the needle by pressing the needle down against any hard surface. At this point the needle may be re-opened by using the normal technique. To use the permanent locking system, close the sheath over the needle by pressing the needle down against any hard surface then, pressing the tip of the sheath with more force until the needle is lodged between the locking tabs, creating a permanent lock.

**The Multi Sample Needle and The Blood Collection Unit are designed to be used as "one" product, or used separately.

807.92(a)(5)

Intended Use: **The SafetyTip™ Multi Sample Needle** is a sterile, multi-sample single-use device for blood collection. The needle is designed with an attached safety sheath, which can be activated to sheath the needle immediately after venipuncture to provide protection from accidental needlesticks. The SafetyTip™ Multi-Sample Needle can be used with any tube holder to perform blood collection (phlebotomy) After use,

immediately dispose of the Multi-Sample Needle in an approved Bio-Hazard container.

807.92(a)(5) continued

Intended Use: **The SafetyTip™ Blood Collection System** is a sterile, multi-sample needle, permanently attached to a sterile tube holder. The needle is used to draw blood from a vein and the tube holder holds the test tubes while the blood is drawn into the tubes. After blood collection, the tubes are then placed in the phlebotomy carriers or refrigeration units and the disposable SafetyTip™ Blood collection System is then discarded into an approved Bio-Hazard container.

807.92(a)(6)

There is one significant technological characteristic of our device compared to predicate devices in that the SafetyTip™ Multi-Sample Needle and the SafetyTip™ Blood Collection System contain a safety "sheath" that is intended to cover the needle after use and before disposal for healthcare worker protection.

807.92(b)(1)

The determination of substantial comparison of the device features, materials, and intended use. Please refer to the substantial equivalence table in this 510(k) submission for more specific details.

807.92(b)(2)

The determination of substantial equivalence is not based on a assessment of clinical performance data. We are planning to conduct clinical trials at medical facilities and institutions as soon as possible, and will submit any relevant information in the form of an addendum if needed. (# 3 of the 510(k) content and format states, "Clinical data is not needed for most devices cleared by the 510(k) process.")

807.92(b)(3)

The conclusions drawn from the non-clinical data is that the SafetyTip™ Multi-Sample Needle and the SafetyTip™ Blood Collection System are substantially equivalent to the commercially available devices on the market today.

807.92(d) The FDA has made no requests at this point in the process of the application.



JUN 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Geneva Burchell
Safety Medical Supply International, Incorporated
69 Hickory Drive, 1st Floor
Waltham, Massachusetts 02451-1011

Re: K993125

Trade Name: SafetyTip® Multi-Sample Needle and
SafetyTip® Blood Collection System
Regulatory Class: II
Product Code: FMI
Dated: April 5, 2000
Received: April 14, 2000

Dear Ms. Burchell:

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.

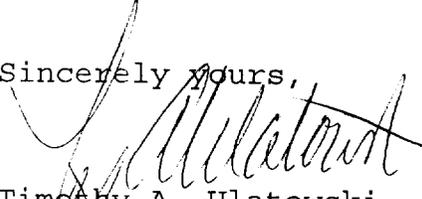
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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): 993125

Device Name: SafetyTip™ Multi-Sample Needle and SafetyTip™ Blood Collection System

Indications for use:

The SafetyTip™ Multi-Sample Needle and SafetyTip™ Blood Collection System is to be used for venous blood collection. The safety sheath helps to prevent accidental needlesticks by sheathing the needle before and after use.

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

Concurrence of CDRH, Office of device evaluation (ODE)

Patricia Cucurto

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

510(k) Number 11993125

(Optional Format 3-10-98)