K021315

AUG 2 1 2002

Attachment 6

510(k) Summary

Device Name

The device trade names and classification names are:

Device Trade Name	Classification Name
Sure-Lok™	Hypodermic Single Lumen Needle

Contact and Address

Anthony P. Martino
V.P. Quality and Regulatory Affairs
Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512
(973) 790-1330 phone
(973) 790-4150 fax

Device Class

Hypodermic Single Lumen Needle has been classified as Class II, 80 FMI. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device.

Predicate Device Information

The predicate devices are the *NeedleTrap™ [510(k) K950098]* and the *Point-Lok™ [510(k) K946289]*.

Intended Use

The Sure-Lok™ secondary needle kit contains a needle w/Sure-Lok™ adapter, sheath, and base stand that is intended for use with standard luer-lock and luer-slip arterial blood gas collection syringes. Following sampling, the needle is inserted into the sheath whereby the Sure-Lok™ adapter engages with the sheath, preventing needle exposure.

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Device Description

The device description of the Sure-Lok™ secondary needle kit is as follows.

- Hypodermic single lumen needle, 20G - 25G, 5/8" to 1½" length.
- Adapter attached to needle with 6% (luer) taper for syringe barrel attachment.
- Needle Sheath that seals the needle tip and locks with the adapter to prevent needle exposure.
- Base Stand that holds the sheath in an upright position during engagement of the needle and sheath.
- Individually packaged and sterilized.

Substantial Equivalence

The Sure-Lok™ device has the following similarities with the predicate devices:

Characteristic	Predicate Devices: NeedleTrap and Point-Lok	Sure-Lok
Intended Use	To protect against accidental needle sticks after needle has been inserted into the device.	Same
Technique	Needle is inserted into device with one-hand.	Same
Needle Point	After insertion into device, needle tip is sealed to prevent sample contamination and blood spattering.	Same
Needle Encapsulation	After insertion into device, the needle is locked into the device and cannot be removed.	Same
Base Configuration	Device has a flat base that sits on a flat surface.	Same
Color	The device is colored orange / red.	Same
Needle Specifications	Can accept needle gage size 12 through 30, 5/8" to 1½" in length, luer slip and luer lock (Point-Lok). Can accept needle gage size 20 through 25, 1" in length, luer slip and luer lock (NeedleTrap)	Same (needle gage size 20 to 25, 5/8" to 1½" in length, luer slip and luer lock)
Training	No training is required to use the device.	Same
Puncture Resistant	Plastics used to encapsulate needles are puncture resistant. Polystyrene (NeedleTrap), Rubber Modified Polystyrene (Point-Lok).	Same (Acrylic)
Point of Use	Device does not interfere with syringe/needle during sampling. The device encapsulates the needle after it has been used.	Same

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510(k) Summary

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Section 807, and based on the information provided in this Premarket Notification, Vital Signs, Inc. concludes that the *Sure-Lok*™ device is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2002

Vital Signs, Incorporated
C/O Mr. Thomas W. Dielmann
Marquest Medical Products, Incorporated
11039 East Lansing Circle
Englewood, Colorado 80112

Re: K021315
Trade/Device Name: Sure-Lok™ Secondary Needle Kit
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 27, 2002
Received: June 28, 2002

Dear Mr. Dielmann:

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) 594-4618. 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,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K021315

Device Name Sure-Lok™ secondary needle kit

Indications for Use The Sure-Lok™ secondary needle kit contains a needle w/Sure-Lok™ adapter, sheath, and base stand that is intended for use with standard luer-lock and luer-slip arterial blood gas collection syringes. Following sampling, the needle is inserted into the sheath whereby the Sure-Lok™ adapter engages with the sheath, preventing needle exposure.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-counter use _____
(per 21 CFR 801.109)

Patricia Cucuzzella

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

510(k) Number: K021315