MAY 12 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for MiniLoc™ Safety Infusion Set

SUBMITTER:
Specialized Health Products®, Inc.
585 West 500 South
Bountiful, Utah 84010

ESTABLISHMENT REGISTRATION NUMBER:
1723684

CONTACT:
Mark Nelson
Manager, Quality and Regulatory Affairs
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DATE PREPARED:
March 7, 2005

NAME OF MEDICAL DEVICE:
Classification Name: Intravascular Administration Set
Common/Usual Name: Huber Needle Intravascular Administration Set
Proprietary Name: MiniLoc™ Safety Infusion Set

DEVICE CLASSIFICATION:
Classification Panel: General Hospital and Personal Use
Class: II
Procode: FPA
Regulation Number: 21 CFR 880.5440

STATEMENT OF SUBSTANTIAL EQUIVALENCE:
LiftLoc® Safety Infusion Set, Specialized Health Products, Inc., Bountiful, UT 84054, (K013394 and K042234).

DEVICE DESCRIPTION:

The MiniLoc™ Safety Infusion Set is a standard non-coring Huber type needle and administration set with an integral safety needlestick prevention feature. The MiniLoc™ Safety Infusion Set is designed for use with a vascular access infusion system and is intended for use as an intravascular administration set to access surgically implanted subcutaneous vascular ports in a standard manner for the purposes of fluid or drug infusion and blood sampling. The MiniLoc™ Safety Infusion Set is supplied sterile and non-pyrogenic, for single use only.

Following conventional placement of the MiniLoc™ Safety Infusion Set's Huber needle into the implanted port and completion of either the prescribed infusion of fluids or blood sample withdrawal, the MiniLoc™ Safety Infusion Set may then be removed from the patient.

Conventional clinical practice is used to remove the MiniLoc™ Safety Infusion Set from the implanted port. Fingers of the non-dominant hand are placed on top of the MiniLoc™ finger tabs to stabilize the port. A one-handed (dominant hand) technique is then used to grasp the integral wings and pull upward to remove the Huber needle from the port. As the needle is removed, the integral safety mechanism is activated and locks a safety shield covering the needle. A tactile feel, an audible click and/or visual confirmation verifies the lockout of the safety shield over the needle. The MiniLoc™ Safety Infusion Set, now with a protected needle, is discarded in a sharps container.

The product has three configurations: A set with and without an adaptable Y-injection site and a set with a needleless adapter attached to the Y-site.

INTENDED USE:

The MiniLoc™ Safety Infusion Set device is a safety intravascular administration set with a non-coring right angle Huber needle, used to access surgically implanted vascular ports. The MiniLoc™ Safety Infusion Set is intended for use in the administration of fluids and drugs, or blood sampling through surgically implanted vascular ports.

The MiniLoc™ Safety Infusion Set will be marketed as a sterile, non-pyrogenic, single use device. The MiniLoc™ Safety Infusion Set should be changed per CDC guidelines, Oncology Nursing Society (ONS), Infusion Nurses Society (INS), or per hospital protocol for Huber needle IV administration sets. The MiniLoc™ Safety Infusion Set may be used in any appropriate patient population.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

It is Specialized Health Products®, Inc.'s conclusion that the MiniLoc™ Safety Infusion Set is substantially equivalent to the following Huber needle intravascular administration set: *LiftLoc® Safety Infusion Set (K013394 and K042234), Specialized Health Products, Inc., Bountiful, UT 84054.*

A summary of the key technological comparisons follows:

- The MiniLoc™ Safety Infusion Set utilizes a right angle Huber needle to access implanted vascular ports, as does the predicate device cited in this submission.
- The MiniLoc™ Safety Infusion Set operates as a standard Huber needle intravascular administration set, as does the Specialized Health Product's Safety Infusion set: *LiftLoc® Safety Infusion Set (K013394 and K042234).*
- The MiniLoc™ Safety Infusion Set is manufactured from the same or similar materials as the predicate device. All materials will meet ISO 10993 requirements for material safety and biocompatibility.
- The MiniLoc™ Safety Infusion Set has a safety feature to help prevent accidental needlestick injuries, as does the *LiftLoc® Safety Infusion Set (K013394 and K042234).*

SUMMARY OF PERFORMANCE TESTING:
Comparative testing has been performed on the MiniLoc™ Safety Infusion Set and the predicate device. Test results indicate that the MiniLoc™ Safety Infusion Set performs in a substantially equivalent manner.

SUMMARY OF SIMULATED USE STUDY:
A total of 500 MiniLoc™ Safety Infusion Sets were successfully inserted by clinicians into simulated tissue and activated. No sharps injuries or failures of the integral needlestick prevention feature/safety mechanism occurred.

CONCLUSION:
The material testing and simulated use data demonstrate that the MiniLoc™ Safety Infusion Set is safe and effective for its intended use, complies with medical device standards, and is substantially equivalent to the following Huber needle intravascular administration set: the *LiftLoc® Safety Infusion Set (K013394 and K042234).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2005

Mr. Mark Nelson
Manager, Quality/Regulatory Affairs
Specialized Health Products®, Incorporated
585 West 500 South #200
Bountiful, Utah 84010

Re: K050600
Trade/Device Name: MiniLoc™ Safety Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 7, 2005
Received: March 10, 2005

Dear Mr. Nelson:

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

Indications For Use

510(k) Number (if known): K050600

Device Name: MiniLoc™ Safety Infusion Set

Indications For Use:

- The MiniLoc™ Safety Infusion Set device is a safety intravascular administration set with a non-coring right angle Huber needle, used to access surgically implanted vascular ports.
- The integral MiniLoc™ Safety Infusion Set safety mechanism is manually activated during the removal of the MiniLoc™ Safety Infusion Set needle from a surgically implanted vascular port. The safety mechanism reduces the risk of accidental needlestick injuries by shielding the needle.
- The MiniLoc™ Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted ports.
- The MiniLoc™ Safety Infusion Set will be marketed as a sterile, non-pyrogenic, single use device.
- The MiniLoc™ Safety Infusion Set may be used in any appropriate patient population.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050600