SECTION 3.0

SEP - 8 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for the *LiftLoc® Safety Infusion Set*

SUBMITTER:
Specialized Health Products®, Inc.
585 West 500 South, Suite 200
Bountiful, Utah 84010

ESTABLISHMENT REGISTRATION NUMBER:
1723684

CONTACT:
Mark Nelson
Director, Quality and Regulatory Affairs
Telephone: 801-298-3360
Fax: 801-298-1759
Email: **marknelson@shpi.com**

DATE PREPARED:
August 17, 2004

NAME OF MEDICAL DEVICE:

Classification Name:	Intravascular Administration Set
Common/Usual Name:	Huber Needle Intravascular Administration Set
Proprietary Name:	LiftLoc® Safety Infusion Set

DEVICE CLASSIFICATION:

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

PREDICATE DEVICE: *LiftLoc® Safety Infusion Set (K013394),* Specialized Health Products®, Inc., Bountiful, UT 84010.

DEVICE DESCRIPTION AND COMPARISON TO CLEARED DEVICE:
The LiftLoc® Safety Infusion Set is a non-coring Huber needle and administration set with an integral safety needlestick prevention feature. The LiftLoc® 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 LiftLoc® Safety Infusion Set is supplied sterile and non-pyrogenic, for single use only.

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

Conventional clinical practice is used to remove the LiftLoc® Safety Infusion Set from the implanted port. Fingers of the non-dominant hand are placed on top of the LiftLoc® Safety Infusion Set's plastic base 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. When the clinician's hands are positioned correctly over the LiftLoc®'s plastic base and the needle is removed, the integral safety mechanism is activated and locks a safety shield covering the needle. An audible click or visual confirmation confirms the lockout of the safety shield over the needle. The LiftLoc® Safety Infusion Set, now with a protected needle, is discarded in a sharps container.

All aspects of the device are the same as the predicate device including intended use and the fundamental scientific technology. The presence of lubrication on the needle (medical grade silicone) is the only difference in the modified device compared to the cleared device. Enhanced labeling is also included in this submission.

The product has two configurations: one with an adaptable Y-injection site and one without. A Patient Comfort Pad is also available as an optional accessory.

INTENDED USE:

The LiftLoc® 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 LiftLoc® Safety Infusion Set is intended for use in the administration of fluids and drugs, or blood sampling through surgically implanted vascular ports.

The LiftLoc® Safety Infusion Set will be marketed as a sterile, non-pyrogenic, single use device. The LiftLoc® 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 LiftLoc® Safety Infusion Set may be used in any appropriate patient population.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

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

Re: K042234
Trade/Device Name: Modification to: LiftLoc® Safety Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 17, 2004
Received: August 27, 2004

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.

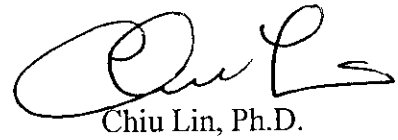
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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,



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

K042234

Indications for Use

510(k) Number (if known): K042234

Device Name: LiftLoc® Safety Infusion Set

Indications for Use:

- The LiftLoc® 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 LiftLoc® Safety Infusion Set safety mechanism is manually activated during the removal of the LiftLoc® 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 LiftLoc® Safety Infusion Set is intended for use in the administration of fluids and drugs, or blood sampling through surgically implanted vascular ports.
- The LiftLoc® Safety Infusion Set will be marketed as a sterile, non-pyrogenic, single use device.
- The LiftLoc® 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 801 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: K042234