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

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

ESTABLISHMENT REGISTRATION NUMBER:
1723684

CONTACT:
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Manager, Quality and Regulatory Affairs
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DATE PREPARED:
October 12, 2001

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

STATEMENT OF SUBSTANTIAL EQUIVALENCE:
- *Millennium Huber Plus Safety Infusion Set (K993848),* Millennium Medical Distribution, Inc., Kennett Square, PA.
- *Butterfly Non-coring Needle Set (K863606),* Cormed, Inc., Sub. C.R. Bard, Inc.(currently marketed by Bard Access Systems, a division of C.R. Bard, as *Winged Infusion Set*), 591 Mahar St., Medina, NY 14103

DEVICE DESCRIPTION:

The LiftLoc™ Safety Infusion Set is a standard non-coring Huber type 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 disc 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™ safety disc 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.

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

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

It is Specialized Health Products®, Inc.'s conclusion that the LiftLoc™ Safety Infusion Set is substantially equivalent to the following Huber needle intravascular administration sets: *Millennium Huber Plus Safety Infusion Set (K993848)* and the Bard Access Systems *Butterfly Non-coring Needle Set (K863606)*. A summary of the key technological comparisons follows:

- The LiftLoc™ Safety Infusion Set utilizes a right angle Huber needle to access implanted vascular ports, as do both predicate devices cited in this submission.
- The LiftLoc™ Safety Infusion Set operates as a standard Huber needle intravascular administration set, as does the Bard Access Systems Huber IV administration set: *Butterfly Non-coring Needle Set (K863606)*. (Currently marketed by Bard Access Systems Systems, a division of C.R. Bard, as *Winged Infusion Set*).
- The LiftLoc™ Safety Infusion Set is manufactured from the same or similar materials as the predicate devices, with the exception of the Patient Comfort Pad. All materials will meet ISO 10993 requirements for material safety and biocompatibility.

- The LiftLoc™ Safety Infusion Set has a safety feature to help prevent accidental needlestick injuries, as does the *Millennium Huber Plus Safety Infusion Set (K993848)*.

SUMMARY OF PERFORMANCE TESTING:

Comparative testing has been performed on the LiftLoc™ Safety Infusion Set and two predicate devices. Test results indicate that the LiftLoc™ Safety Infusion Set performs in a substantially equivalent manner.

SUMMARY OF SIMULATED USE STUDY:

A total of 500 LiftLoc™ Safety Infusion Sets were successfully inserted by clinicians into an actual implantable port through 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 LiftLoc™ 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 sets: *Millennium Huber Plus Safety Infusion Set (K993848)* and the Bard Access Systems *Butterfly Non-coring Needle Set (K863606)*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K013394
Trade/Device Name: LiftLoc™ Safety Infusion Pump
Regulation Number: 880.5440 and 880.5965
Regulation Name: Huber Needle Intravascular Administration Set
Regulatory Class: II
Product Code: FPA and LJT
Dated: October 12, 2001
Received: October 15, 2001

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 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,

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

Enclosure

NOV 0 8 2001

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013394

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucinotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013394

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)