510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for SafeStep® MAX™ Power-Injectable Infusion Set

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

ESTABLISHMENT REGISTRATION NUMBER:
1723684

JAN 25 2008

CONTACT:
Mark Nelson
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DATE PREPARED:
January 25, 2008

NAME OF MEDICAL DEVICE:
Regulation Name: Intravascular Administration Set
Common/Usual Name: Huber Needle Intravascular Administration Set
Proprietary Name: SafeStep® MAX™ Power-Injectable Infusion Set

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

PREDICATE DEVICES:
Trade/Device Name: *Luther Safety Huber Needle (Re-branded as "SafeStep® Safety Huber Needle Set") (K040527, K021565)*
Regulation Name: Intravascular Administration Set
Common/Usual Name: Huber Needle Intravascular Administration Set
Regulation Name: Intravascular Administration Set
Classification Panel: General Hospital and Personal Use
Regulatory Class: II
Product Code: FPA
Regulation Number: 21 CFR 880.5440

Trade/Device Name: *PowerLoc™ Safety Infusion Set (K060812)*
Regulation Name: Intravascular Administration Set
Common/Usual Name: Huber Needle Intravascular Administration Set
Regulation Name: Intravascular Administration Set
Classification Panel: General Hospital and Personal Use
Regulatory Class: II
Product Code: FPA
Regulation Number: 21 CFR 880.5440

Trade/Device Name: *Lifeguard Safety™ Infusion Set (K062414)*
Regulation Name: Intravascular Administration Set
Common/Usual Name: Port Access Infusion Set
Regulation Name: Intravascular Administration Set
Classification Panel: General Hospital
Regulatory Class: II
Product Code: FPA
Regulation Number: 21 CFR 880.5440

Trade/Device Name: *Gripper Plus® P.A.C. Needle (K070116)*
Regulation Name: Intravascular Administration Set
Common/Usual Name: Huber Needle Intravascular Administration Set
Regulation Name: Intravascular Administration Set
Classification Panel: General Hospital and Personal Use
Regulatory Class: II
Product Code: FPA
Regulation Number: 21 CFR 880.5440

DEVICE DESCRIPTION:

The SafeStep® MAX™ Power-Injectable Infusion Set is a standard non-coring Huber type needle and administration set with an integral safety needlestick prevention feature.

The SafeStep® MAX™ Power-Injectable Infusion Set is a standard non-coring intravascular administration set with a non-coring Huber type right angle needle and a manually activated needle-stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The device is used to access surgically implanted vascular ports and is indicated for use in the administration of fluids and drugs, as well as blood sampling.

The SafeStep® MAX™ Power-Injectable Infusion Set is also indicated for power injection of contrast media into the central venous system only through an implanted port that is also

indicated for power injection. The maximum recommended infusion rate is 5 ml/s for 19 gauge and 20 gauge needles. and 2 ml/s for 22 gauge needles.

The device functions in a similar manner to all the predicate devices. The insertion site is prepared and the device is primed using a 10 ml syringe containing normal saline and inserted into the port septum. Patency is confirmed and the device is dressed per institutional protocol. Removal of the device is accomplished by flushing per institutional protocol, stabilizing the base of the device by securely holding the base down and firmly pulling the textured handle up until you feel a firm stop and the needle is locked into the safety position. Dispose the set into a sharps container.

INTENDED USE:

The intended use of the SafeStep® MAX™ Power-Injectable Infusion Set has not changed when compared to the predicate devices. This is the same intended use as the predicates SafeStep® Huber Needle Set(K040527), PowerLoc™ Safety Infusion Set (K060812), Lifeguard Safety® Safety Infusion Set (K062414) and Gripper Plus® Power P.A.C. Needle (K070116).

The SafeStep® MAX™ Power-Injectable Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. The intended use has not changed from that of the predicate devices.

INDICATIONS FOR USE:

The SafeStep® MAX™ Power-Injectable Infusion Set device is an intravascular administration set with a non-coring right angle needle and manually activated needlestick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The device is used to access surgically implanted vascular ports.

The SafeStep® MAX™ Power-Injectable Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with ports that are indicated for power injection of contrast media into the central venous system, the SafeStep® MAX™ Power-Injectable Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s for 19 gauge and 20 gauge needles, and 2 ml/s for 22 gauge needles.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? No. The Indications for Use for the infusion set were expanded to include power injection of contrast media into surgically implanted ports that are also indicated for power injection.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Not in all regards. The SafeStep® MAX™ Power-Injectable Infusion Set has some minor differences from the predicate devices. The basic fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness? Yes, the expanded indication to include power injection of contrast media through a power injection indicated port could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

The FDA's *Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification] Submissions [510(k)]*, dated April 15, 2005.

Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features, August 9, 2005.

Sterilization requirements of ISO 11135:1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.*

Sterilization requirements of ISO 11137: 2006, *Sterilization of health care products – Radiation.*

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating devices with an indirect blood path with a contact duration of >24 hours to 30 days.

These and other standards were used to determine the appropriate methods for evaluating the modified device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrated that the SafeStep® MAX™ Power-Injectable Infusion Set is substantially equivalent to the noted predicate devices.

CONCLUSION

The SafeStep® MAX™ Power-Injectable Infusion Set met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the SafeStep® MAX™ Power-Injectable Infusion Set is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices: *SafeStep® Huber Needle Set(K040527), PowerLoc™ Safety Infusion Set (K060812), Lifeguard Safety® Safety Infusion Set (K062414) and Gripper Plus® Power P.A.C. Needle (K070116).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

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

Re: K073050
Trade/Device Name: SafeStep® MAX™ Power-Injectable Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 25, 2007
Received: October 29, 2007

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

K073050

Indications For Use

510(k) Number (if known): _____

Device Name: **SafeStep® MAX™ Power-Injectable Infusion Set**

Indications For Use:

The SafeStep® MAX™ Power-Injectable Infusion Set device is an intravascular administration set with a non-coring right angle needle and manually activated needlestick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The device is used to access surgically implanted vascular ports.

The SafeStep® MAX™ Power-Injectable Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with ports that are indicated for power injection of contrast media into the central venous system, the SafeStep® MAX™ Power-Injectable Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s for 19 gauge and 20 gauge needles, and 2 ml/s for 22 gauge needles.

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: K073050