K013871

MAR 2 9 2002

Proprietary to Horizon Medical Products, Inc.

510(k) Summary of Safety and Effectiveness
LifeGuard™ Safety Infusion Set

Date Summary Was Prepared: March 5, 2002

Submitter's Information:

Horizon Medical Products, Inc.
One Horizon Way
Manchester, Georgia 31816

Telephone Number: 706-846-3126

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Contact Person: Patricia Jones, Regulatory Affairs Associate

Device Trade Name: LifeGuard™ Safety Infusion Set

Device Common Name: Safety Infusion Set

Classification Name: Intravascular Administration Set

Classification Panel: General Hospital Use

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To:

The LifeGuard™ Safety Infusion Set is substantially equivalent to

- Horizon Medical Products LifePort® Infusion Set (K921674)
- Millennium Safety Non-coring Plus Infusion Set (K993848)

Device Description:

The LifeGuard™ Infusion Set is a standard 90° non-coring needle intravascular administration set with a sharps injury protection. The LifeGuard™ Infusion Set is designed for use with vascular access devices. The needle is inserted into the vascular access port in a standard manner for fluid infusion or for blood sampling.

The components that comprise the LifeGuard™ Safety Infusion Set includes the following: a PVC tubing set; a white clamp to prevent fluid flow; a universal female luer lock connector to connect to infusion/aspiration devices; a white cap to close the female luer; a winged needle holder to secure the infusion set to the patient with a pre-attached 90° non-coring needle to access the implanted port and allow the user to pull the needle up into the safety position; a needle trap encapsulates the needle after de-accessing the needle from the implanted port; and a needle guard shrouds the needle before use. Some models include a Y-site as an alternate female luer injection site with an additional white cap and white clamp to prevent fluid flow. A thermoformed tray with a heat sealed tyvek lid provides a sterile barrier.

The LifeGuard™ Safety Infusion Set is fabricated from biocompatible, medical grade materials. The LifeGuard™ Safety Infusion Sets are supplied as sterile, non-latex, nonpyrogenic, intended for single use only and are manufactured out of non-DEHP PVC.

De-accessing the needle is done as with any standard non-coring needle, using a one-handed (dominant hand) technique to remove the needle while stabilizing the port with the nondominate hand. As the needle is removed, the passive sharps injury protection feature is actuated by sliding the needle holder upward, which encapsulates the needle within the needle trap.

Indication for Use:

The LifeGuard™ Safety Infusion Set is used to access implanted vascular ports to administer fluids and/or to withdraw blood. The LifeGuard™ Safety Infusion Set facilitates safe removal of the needle by encapsulating the needle during vascular port de-accessing to help prevent needlestick injuries.

Technological Characteristics:

The LifeGuard™ Safety Infusion Set is manufactured from the same materials as the LifePort® Infusion Set. The current LifePort® Infusion Set does not have a sharps injury protection. The LifeGuard™ Safety Infusion set needle; components and safety mechanism are all fabricated out of medical grade materials. The LifeGuard™ Safety Infusion Set operates the same as a standard non-coring needle with the addition of a safety feature to help prevent needlestick injuries.

Performance Data

Horizon Medical Products, Inc. certifies that the materials used to manufacture the winged needle holder, base and needle trap are the same materials used in the manufacture of the LifePort® Infusion Set predicate device (refer to Biocompatibility Matrix). The same manufacturing process and type of sterilization that are used for the manufacture of Horizon's predicate device and Horizon's other legally marketed medical devices will be used to manufacture and sterilize the LifeGuard™ Infusion Set. The cannula tubing, Y-connector (minus synthetic polyisoprene injection port with shinkwrap), non-coring needle, female luer connector, white clamp and white cap remain identical to the LifePort® Infusion set predicate device. Since the critical features of the device have not changed, performance results will be identical to the predicate device (LifePort® Infusion Set). Testing was performed on the LifeGuard™ Safety Infusion Set to show adequacy of the device design and substantial equivalency.

A Simulated Use Study (n=500) demonstrated that the failure rate of the sharps injury protection feature is less than 1.1% (at 95% confidence) or less than 1.5% (at 99% confidence). Test results demonstrated that the LifeGuard™ Safety Infusion Set is substantially equivalent to the noted predicate devices commercially in distribution for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2002

Ms. Patricia D. Jones
Regulatory Affairs Associate
Horizon Medical Products, Incorporated
1 Horizon Way
Manchester, Georgia 31816

Re: K013871
Trade/Device Name: LifeGuard™ Safety Infusion Set
Regulation Number: 880.5440 and 880.5965
Regulation Name: Intravascular Administarion Set
Regulatory Class: II
Product Code: FPA and LJT
Dated: March 5, 2002
Received: March 6, 2002

Dear Ms. Jones:

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,

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

Enclosure

IV. Indication for Use Statement

PREMARKET NOTIFICATION

INDICATION FOR USE STATEMENT

510(k) Number: K013871

Device Name: **LifeGuard™ Safety Infusion Set**

Indication for Use:

The LifeGuard™ Safety Infusion Set is used to access implanted vascular ports to administer fluids and/or to withdraw blood. The LifeGuard™ Safety Infusion Set facilitates safe removal of the needle by encapsulating the needle during vascular port de-accessing to help prevent needlestick injuries.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K013871