K052722

LifeShield® Latex-Free Microbore Extension Set
Special 510(k) / September 2005

NOV - 2 2005

Special 510(k) Summary

Name of Submitter:

Hospira, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045
Owner/Operator #: 9063339

Manufacturer and Establishment Registration Number:

Manufacturer:	Sterilization Site:
Hospira Holdings De Costa Rica, LTD Zona Franca Global La Aurora De Heredia, Costa Rica Establishment Registration #: 9615050	Hospira, Inc. – Rocky Mount Hwy. 301 North P.O. Box 2226 Rocky Mount, NC 27801 Establishment Registration #: 1021343

Proprietary or Trade Name of Proposed Device: LifeShield® Latex-Free Microbore Extension Set
Common Name: Fluid Delivery Tubing
Device Classification, Pancode and ProCode: Class II, 80-FPK
Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Fluid Delivery Tubing. Fluid Delivery Tubing is regulated within 21 CFR 880.5440.

Intended Use Indications for Use:
The LifeShield® Latex-Free Microbore Extension Set is intended for the delivery of fluids from a container to a patient's vascular system.

Proposed Device Description:
The LifeShield® Latex-Free Microbore Extension Set consists of DEHP-plasticized polyvinyl tubing with a secure lock male adapter and air filter assembly on one end and locking female Luer adapter with removable CLAVE® Connector on the other end.

Summary of Substantial Equivalence
The LifeShield® Latex-Free Microbore Extension Set as described in this submission utilizes components (i.e., set tubing and High Pressure CLAVE) from the predicate LifeShield® Latex-Free, Primary IV Pump Set with Distal Microbore Patient Line (K033576) and is substantially equivalent to the predicate LifeShield® Microbore Extension Set (K912103) with respect to the following characteristics:

Similarities:
1) The extension sets are intended for the delivery of fluids from a container to a patient's vascular system.
2) The devices are provided with a non-pyrogenic, sterile fluid-path and are intended for one-time use.
3) The technology and operating principles (i.e., administration/infusion of intravenous medications to a patient's vascular system with the assistance of gravity or an infusion pump are the same, and
4) The materials of construction are the same.

Differences:
1) The inner and outer diameter of the set tubing for the modified LifeShield® Latex-Free Microbore Extension Set is larger and the maximum infusion pressure for the set is specified on the package label.

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Statement of Safety and Effectiveness

The LifeShield® Latex-Free Microbore Extension Set meets the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate LifeShield® Extension Sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

Thomas Kozma, Ph.D.
Associate Director, Global Device Regulatory Affairs
Hospira, Incorporated
Department 0389, Building H2
275 North Field Drive
Lake Forest, Illinois 60045

Re: K052722
Trade/Device Name: Lifeshield Latex-free Microbore Extension Set, Model 14949
Regulation Number: 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA, FPK
Dated: September 28, 2005
Received: September 29, 2005

Dear Dr. Kozma:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use with power injection and high power infusion systems have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0343. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K052722

Device Name: **LifeShield® Latex-Free Microbore Extension Set**

Indications for Use:

The LifeShield® Latex-Free Microbore Extension Set is intended for the delivery of fluids from a container to a patient's vascular system.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (Part 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: K052722