



Food and Drug Administration  
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June 10, 2015

Hospira, Incorporated  
Mr. David Blonski  
Director Regulatory Affairs  
375 N. Field Drive  
Lake Forest, IL 60046

Re: K142622  
Trade/Device Name: Burette Sets  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: FPA  
Dated: December 18, 2014  
Received: December 19, 2014

Dear Mr. Blonski:

This letter corrects our substantially equivalent letter of January 15, 2015.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
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for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142622

Device Name

Hospira Burette Set

Indications for Use (Describe)

Hospira Burette sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**Section 5 510(k) Summary**

K142622

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 for Hospira Burette Sets.

<b>Submitter Information</b>	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60046
Phone number	(224) 212-5010
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	David Blonski, Director Regulatory Affairs
Date prepared	09/19/2014
<b>Name of device</b>	
Trade or proprietary name	Burette Sets
Common or usual name	I.V Administration Sets
Classification name	Intravascular Administration Set, 21 CFR 880.5440, Class II
<b>Product Code(s)</b>	FPA
<b>Legally marketed device(s) to which equivalence is claimed</b>	LifeShield Vision Infusion Sets – K113683
<b>Reason for 510(k) submission</b>	The changes addressed in this submission include: <ul style="list-style-type: none"> <li>• Modification to Secure Lock Male Luer</li> </ul>
<b>Device description</b>	The Hospira Burette Sets with Secure Lock are intended for use as gravity sets. Hospira Burette sets are comprised of various components including the following: male luer adapter with cap, tubing, flow control device, piercing pin assembly, burette assembly and injection site assembly. Burette sets are configured to ensure the intended use of the device is met. Hospira Burette sets are intended for the delivery of fluids from a container to a patient’s vascular system. The sets are disposable devices for single patient use.
<b>Intended Use of Device</b>	Hospira Burette sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient’s vascular system.

<b>Summary of the technological characteristics of the device compared to the predicate device</b>		
<b>Characteristic</b>	<b>Predicate</b>	<b>Proposed Device</b>
Indications for Use	LifeShield Infusion Sets are intended for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.	Hospira Burette sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.
Design and Materials of Construction	The design and materials of construction are as cleared under the predicate 510(k)	The design and materials of construction remain the same as the predicate product with the following exceptions: 1. The male luer adapter material is changing to an alternate acrylic material. 2. Minor dimensional modifications are being made to the male luer adapter to enhance connection with female luers.
Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for Hospira Burette Sets meet the applicable material test requirements for ISO 10993	New data has been generated demonstrating that all materials of construction for Hospira Burette Sets meet the applicable material test requirements for ISO 10993.
Summary of Performance Testing	Performance testing was conducted to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable.  The product Sterility Assurance Level is $10^{-6}$ .	New performance data has been generated to ensure the device performs as intended in accordance with ISO 594-1, ISO 594-2, ISO 8536-4. All testing is acceptable.  The product Sterility Assurance Level is $10^{-6}$ .

## Conclusion

Hospira Burette Sets meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the LifeShield Vision Infusion Sets cleared under K113683.