K133602

JAN 24 2014

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92. ADD-Vantage ADDaptor™ vial adapter transfer device

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H2 275 North Field Drive Lake Forest, IL. 60045
Phone number	(224) 212-5316
Fax number	(224)-212-5401
Establishment Registration Number	Owner/Operator #9063339 Establishment registration number #3005579246
Name of contact person	Karen Keener
Date prepared	October 01, 2013
Name of device	
Trade or proprietary name	ADD-Vantage ADDaptor™
Common or usual name	Binary connector transfer device
Classification name	Set I.V., Fluid Transfer
Classification panel	Class II
Regulation	21-CFR-Part-880.5440
Product Code(s)	LHI
Legally marketed device(s) to which equivalence is claimed	B. Braun addEASE (K090905)
Reason for 510(k) submission	Accessory to the ADD-Vantage system which will allow the use of a standard 20mm powdered drug vial to be used with the ADDVantage diluent bag.
Device description	ADD-Vantage ADDaptor™ vial adapter transfer device is a double ended vial transfer device which allows the use of a 20mm single dose standard drug vial, to be connected to an ADD-Vantage diluent container bag.

Intended use of the device	The ADD-Vantage ADDaptor™20 mm binary connector is a double ended transfer device intended for use in a pharmacy setting or patient care area, by trained clinicians, to connect an ADD-Vantage diluent solution bag to a 20 mm drug vial for reconstituting or mixing the drug in the vial with the solution in the bag.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Predicate Device	Proposed Device
Intended Use	Vial Transfer of Lyophilized Molecule(s)	Same
Transfer adapter Vial Type	20mm	Same
Diluent Bag	B. Braun Diluent Containers	ADD-Vantage Diluent Container(s)
Device components	Transfer Adapter Sterile Cap _Qty 2	Same Same
Vial Access	Plastic Spike	Same
Vial Retention	Plastic Snaps/Grips	Same
Diluent Bag connection	Needle (17gauge)	Threads, Face Seal
Reconstitution	Milking of system	Same
Transfer Adapter	Polycarbonate	ABS-White, Polypropylene- purple
Sterile Caps Material	Not Available	Low density polyethylene (LDPE)
Manufacturing Assembly	Assume Ultrasonic Welding	Same
Manufacturing Assembly	Assume Ultrasonic Welding	Interference fit sterile caps
Sterilization	Gamma	Same
Biocompatibility	Assume 10993-1	Per 10993-1
Principle of Operation	Same	Same

Performance Data		
Summary of non-clinical tests conducted for determination of substantial equivalence*		
Performance Test Summary-New Device		
Characteristic	**Standard/Test Method**	**Standard / Test Title**	**Device Performance**
Biocompatibility	ISO 10993-1 : 2009/ AC 2010	Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process	Pass
Biocompatibility	ISO 10993-5: 2009	Biological evaluation of medical devices- Part 5: Cytotoxicity	Pass
Biocompatibility	ISO 10993-10: 2010	Biological evaluation of medical devices- Part 10: Sensitization/ Irritation / Intracutaneous Reactivity	Pass
Biocompatibility	ISO 10993-11:2006	Biological evaluation of medical devices- Part 11: Systemic Toxicity (Acute)	Pass
Biocompatibility	ISO 10993-4: 2002 AC: 2006	Biological evaluation of medical devices- Part 4: Hemocompatibility	Pass
Sterilization	ANSI/AAMI/ISO 11137-2:2012	Sterilization of health care product-Radiation- Establishing the sterilization dose	Pass
Sterilization	ANSI/AAMI/ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods- Part1: Estimation of population of microorganisms on products.	Pass
Sterilization	ANSI/AAMI/ISO 11737-2:2009	Sterilization of medical devices-Microbiological methods- Part 2: Tests of sterility performed in the definition, validation and	Pass

		maintenance of a sterilization process	
Performance	ISO 8536-4 :2010	Infusion Equipment for medical use – Part 4: Infusion sets for single use, gravity feed	Pass
Performance	ISO 8536-6: 2009	Infusion equipment for medical use – Part 6:Freeze drying closures for infusion bottles	Pass

Summary discussion of Bench Performance Data

The ADD-Vantage ADDaptor™ vial adapter transfer device has passed all specified test requirements.

The validation and verification testing have confirmed these devices meet user needs and design inputs for a vial adapter.

Testing also confirmed physical attributes and device performance meets requirements of the standards listed in the "Performance Test Summary-New Devices" table above. These standards address sterility, biocompatibility, and particulate.

Conclusions drawn from non-clinical and clinical data

Statement of Safety and Efficacy:

The ADD-Vantage ADDaptor™ vial adapter transfer device

meets the functional claims, and intended use as described in the product labeling.

The safety and effectiveness, are substantially equivalent to the predicate B. Braun addEASE 20MM Binary Connector cleared under 510(k) K090905 April 27, 2009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 24, 2014

Hospira, Incorporated
C/O Ms. Karen Keener
Regulatory Affairs
275 Field Drive, D-393, Bldg H2
LAKE FOREST IL 60045

Re: K133602
Trade/Device Name: ADD-Vantage ADDaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Set I.V., Fluid Transfer
Regulatory Class: II
Product Code: LHI
Dated: November 25, 2013
Received: November 26, 2013

Dear Ms. Keener:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133602

Device Name
ADD-Vantage ADDaptor™Vial Adapter transfer device

Indications for Use *(Describe)*
The ADD-Vantage ADDaptor™20 mm binary connector is a double ended transfer device intended for use in a pharmacy setting or patient care area, by trained clinicians, to connect an ADD-Vantage diluent solution bag to a 20 mm drug vial for reconstituting or mixing the drug in the vial with the solution in the bag.

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)*

FDA

Digitally signed by Richard C. Chapman
Date: 2014.01.24 16:13:36 -05'00'

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