October 21, 2020

West Pharmaceutical Services AZ, Inc.
℅ Di Wu
Senior Regulatory Affairs Specialist
West Pharmaceutical Services AZ, Inc.
14677 North 74th St.
Scottsdale, Arizona 85260

Re: K201415
Trade/Device Name: Vial2Bag Advanced™ 20mm Admixture Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: September 21, 2020
Received: September 23, 2020

Dear Di Wu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201415

Device Name
Vial2Bag Advanced™ 20mm Admixture Device

Indications for Use *(Describe)*
The Vial2Bag Advanced™ 20mm Admixture Device is indicated to serve as a connection between a 50, 100 or 250mL IV bag, vial with 20mm closure, and an external IV administration set. The integrated Vial Adapter makes it possible to reconstitute and/or admix drugs prior to administration to the patient.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(K) SUMMARY-K201415

5.1 SUBMITTER

Applicant:

West Pharmaceutical Services AZ, Inc.
14677 North 74th St.
Scottsdale, Arizona 85260

Manufacturer:

West Pharmaceutical Services AZ, Inc.
14677 North 74th St.
Scottsdale, Arizona 85260

Contact Person:

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Date Prepared: October 21, 2020

5.2 DEVICE

Trade Name:	Vial2Bag Advanced™ 20mm Admixture Device
Common/Usual Name:	Vial2Bag Advanced™ 20mm Device
Regulation Name:	Intravascular Administration Set
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

5.3 PREDICATE DEVICE

VIAL-MATE Reconstitution Device, K142600

5.4 DEVICE DESCRIPTION

Device Design

The Vial2Bag Advanced™ 20mm Admixture Device is a single use, fluid transfer device that allows for the reconstitution and transfer of fluids from drug vials into the IV bag containing infusion solution, through the IV bag administration port. The device consists of the body, Protector, IV Port, and an integrated vial adapter. The device is provided as a sterile, non-pyrogenic product. The device is intended to be used with standard drug vials with a seal diameter of 20mm and an elastomeric stopper. The Vial2Bag Advanced™ 20mm Admixture Device is designed to work with a standard 50, 100, or 250mL IV bag and an external IV administration set. The device is limited to a single device configuration. Users should not attach a Vial2Bag Advanced™ 20 mm Admixture Device to another Vial2Bag Advanced™ 20mm Admixture Device. The device does not contain any medicinal substances and there are no additional accessories needed or provided with the Vial2Bag Advanced™ 20mm Admixture Device for the device to meet its intended purpose.

Principle of Operation

The Vial2Bag Advanced™ 20mm Admixture Device is operated by manual process. The Vial Adapter is first attached to the drug vial, and after removing the Protector, the IV spike is then connected to the administration port of the IV bag. Fluid is transferred from the IV bag to the drug vial to reconstitute/dilute the drug prior to being transferred back to the IV bag. The IV administration set is then connected to the device's IV Port followed by administration to patient.

5.5 INDICATION FOR USE

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Both the subject and predicate devices have the same intended use for the reconstitution and transfer of drug content from the vial into the IV bag. Both devices are intended for use in healthcare environments by clinically trained healthcare professional providers to aid and support prescribed treatment and therapy.

5.6 TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Vial2Bag Advanced™ 20mm Admixture Device, subject of this Traditional 510(k) is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate device VIAL-MATE Reconstitution Device, which is cleared under K142600.

A comparison of the technological characteristics is summarized in the table below:

Table 5-1: Summary of Substantial Equivalence Comparison

Areas for Comparison	**Subject Device:** Vial2Bag Advanced™ 20mm Admixture Device	**Predicate Device:** VIAL-MATE Reconstitution Device	**Comparison**
Indication for Use	The Vial2Bag Advanced™ 20mm Admixture Device is indicated to serve as a connection between a 50, 100, or 250ml IV bag, vial with 20mm closure, and an external IV administration set. The integrated Vial Adapter makes it possible to reconstitute and/or admix drugs prior to administration to the patient.	To provide the pharmacist or health practitioner a means of connecting a standard 20mm single dose drug vial to an I.V. solution container without mixing the vial contents with the diluent until immediately before administration of the reconstituted drug to the patient.	**Different** (Both have the same intended use for the reconstitution and transfer of drug content from the vial into the IV bag)
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**
Sterility	Sterile	Sterile	**Identical**
Sterilization Method	Ethylene Oxide	Irradiation	**Different**
Operation Principle	Manual	Manual	**Identical**
Design	Made of plastic material, featuring a Vial Adaptor to access the drug content in the 20mm vial, an IV Spike integrated for the connection to a standard IV bag utilizing the	Made of plastic material, featuring a Vial gripper to access to the drug content in the 20mm vial and a port adaptor for the connection to	**Different**

Areas for Comparison	Subject Device: Vial2Bag Advanced™ 20mm Admixture Device	Predicate Device: VIAL-MATE Reconstitution Device	Comparison
	administration port, and a twist off which after removal opens the IV port for connection to the IV administration set.	the VIAFLEX bag utilizing the medication port.	
Drug	Powdered or liquid drug	Powdered drug	**Different**
Vial Size	20mm	20mm	**Identical**
Bag System	Standard IV bag	VIAFLEX bag	**Different**
Bag Size	50, 100, 250mL	50, 100, 250mL	**Identical**
Single/inline configuration	Single configuration only Do not attach one device to another device.	Single configuration only Do not attach one device to another device.	**Identical**

The difference in the technological characteristics between the subject and predicate device have been identified as below:

(1) The predicate device is designed to attach to a 50, 100, or 250 mL VIAFLEX Bag utilizing the medication port of the IV bag, while the subject device, Vial2Bag Advanced™ 20mm Admixture Device, is designed to connect to a 50, 100, or 250mL standard IV bag utilizing the IV port.

(2) The predicate device does not connect to an external IV administration set while the subject device Vial2Bag Advanced™ 20mm Admixture Device contains an IV port with twist off for the connection with any commercially available IV administration set.

(3) The connection with the IV bag IV port and the external IV administration set places Vial2Bag Advanced™ 20mm Admixture Device directly into the administration path while the predicate connects to the medication port of the bag and does not become part of the administration path.

(4) The predicate device is for use with powdered drug and the subject device is for use with powered or liquid drug.

(5) The predicate device and the subject device are made of plastic material. The detailed chemical formulation used in the materials of construction are likely different. Biocompatibility testing was conducted to evaluate the materials of the subject device.

(6) The sterilization method for the predicate device is irradiation, while Vial2Bag Advanced™ 20mm Admixture Device is ethylene oxide. The sterilization method was evaluated in the subject device.

5.7 PERFORMANCE DATA

The following non-clinical data were provided in support of the substantial equivalence determination.

Performance Testing

Performance testing was conducted to ensure that the Vial2Bag Advanced™ 20mm Admixture Device met the applicable design and performance requirements throughout its shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. A list of non-clinical bench performance tests that were completed on the device are summarized below:

Conformity to Standard:

ISO 8536-42010/ Amd.1:2013

Additional Performance Testing to internal specifications:

- Vial Adaptor Tensile Detachment Force
- Vial Adaptor Torsional Breakage
- IV Port Tensile Detachment Force
- Vial Adaptor Wings Breakage
- Vial Attachment Force
- Vial Detachment Force
- Twist Off Opening Torque from IV Port
- Leakage after Removal of Twist Off
- Leakage at the Vial Adapter and Stopper Interface
- Short Circuit Test
- Vial Adaptor Color Identification
- Dose Concentration of Delivery Profile
- Transfer of Vial Contents to the Administration Set
- Transfer of Vial Contents to the Bag
- Dimensional Measurements of the IV spike lumens
- Dimensional Measurements of the VA retention feature

Performance testing and risk management review indicate all product design requirements are verified and the residual risk level is acceptable based on the test results. Together, objective evidence satisfies the product requirements and the results support a determination of substantial equivalence.

Biocompatibility Testing

In accordance with ISO 10993-1, the Vial2Bag Advanced™ 20mm Admixture Device is classified as an externally communicating device with prolonged contact duration (>24 hours to 30 days) and blood path indirect contact. The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA Guidance: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process."* The following biocompatibility tests has been successfully conducted on the Vial2Bag Advanced™ 20mm Admixture Device:

Cytotoxicity (Tested to ISO 10993-5:2009)

Sensitization (Tested to ISO 10993-10:2010)

Intracutaneous Reactivity (Tested to ISO 10993-10:2010)

Acute Systemic Toxicity (Tested to ISO 10993-11:2017)

Material Mediated Pyrogenicity (Tested to ISO 10993-11:2017)

Systemic (Subacute) Toxicity (Tested to ISO 10993-11: 2017)

ASTM Hemolysis (Tested to ISO 10993-4: 2017)

Particulate Testing

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.* The sterilization method provides a sterility assurance level (SAL) of 10^{-6}.

5.8 CLINICAL DATA

No clinical trial was performed for Vial2Bag Advanced™ 20mm Admixture Device.

5.9 CONCLUSION

In summary, the Vial2Bag Advanced™ 20mm Admixture Device, subject of this Pre-market Notification, is considered to be substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate device, VIAL-MATE Reconstitution Device (K142600).