December 1, 2023

West Pharma Services IL, Ltd.
% Lynn Lundy
Sr. Director, Regulatory Affairs
West Pharmaceutical Services, Inc.
530 Hermon O. West Drive
Exton, Pennsylvania 19341

Re: K230988
Trade/Device Name: Vial2Bag Advanced® 13mm Admixture Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: November 3, 2023
Received: November 3, 2023

Dear Lynn Lundy:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230988

Device Name
Vial2Bag Advanced® 13mm Admixture Device

Indications for Use *(Describe)*
The Vial2Bag Advanced® 13mm Admixture Device is indicated to serve as a connection between a 50, 100 or 250mL IV bag, vial with 13mm 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. Indicated for adolescent and adult patients only.

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.

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K230988 - 510(K) SUMMARY

1 SUBMITTER

Applicant:

West Pharma. Services IL, Ltd.
4 Hasheizaf St.
Ra'anana, Israel 4366411
Facility Establishment Registration Number: 3000223297

Manufacturer:

West Pharma. Services IL, Ltd.
4 Hasheizaf St.
Ra'anana, Israel 4366411
Facility Establishment Registration Number: 3000223297

Contact Person:

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Date Prepared: 06 April 2023

2 DEVICE

Trade Name:	Vial2Bag Advanced® 13mm Admixture Device
Common/Usual Name:	I.V. Fluid Transfer Set
Regulation Name:	Intravascular administration set
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

3 PREDICATE DEVICE

Vial2Bag Advanced 20mm Admixture Device; K201415

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4 DEVICE DESCRIPTION

4.1 Device Design and Operation

The subject Vial2Bag Advanced® 13mm Admixture Device is being developed as a new offering to the market.

The Vial2Bag Advanced® 13mm Admixture Device is a single use, fluid transfer device that allows for 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 13mm and an elastomeric stopper. The Vial2Bag Advanced® 13mm device is designed to work with a standard 50, 100, or 250mL IV bag and an external IV infusion set. Users should not attach a Vial2Bag Advanced device to another Vial2Bag Advanced Device. The device does not contain any medicinal substances and there are no additional accessories needed or provided with the Vial2Bag Advanced 13mm Device for the device to meet its intended purpose.

4.2 Principle of Operation

The Vial2Bag Advanced® 13mm 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 the patient.

5 INDICATIONS FOR USE

The Vial2Bag Advanced® 13mm Admixture Device is indicated to serve as a connection between a 50, 100 or 250mL IV bag, vial with 13mm 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. Indicated for adolescent and adult patients only.

6 TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALAENCE

Both the subject and predicate devices have the similar intended uses 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. The predicate device is indicated for general use with a vial with 20mm closure and the subject device is indicated to be used with a vial with a 13mm closure for adolescent and adult patients only. Human Factors, Performance and Biocompatibility testing confirmed the subject device accommodating a smaller 13mm drug vial size and the adolescent and adult patient population do not raise new or additional concerns regarding device safety profile or clinical effectiveness.

A summary comparing the subject device and the predicate device are provided below:

Table 6-1: Substantial Equivalence Comparison Table

Areas for Comparison	**Subject Device** Vial2Bag Advanced® 13mm Admixture Device	**Predicate Device (K201415):** Vial2Bag Advanced® 20mm Admixture Device	**Comparison**
General Information			
Indications for Use	To serve as a connection between a 50, 100, or 250ml IV bag, vial with 13mm closure, and an external IV administration set. The integrated Vial Adapter makes it possible to reconstitute and/or admix drugs. Indicated for adolescent and adult patients only.	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.	**Difference #1 –** Human Factors, Performance and Biocompatibility testing confirmed the subject device accommodating a smaller 13mm drug vial size and the adolescent and adult patient population do not raise new or additional concerns regarding device safety profile or clinical effectiveness.
Contraindications	None known	None known	**Identical**
Intended User Population	Intended for use by Healthcare Professionals (HCPs)	Intended for use by Healthcare Professionals (HCPs)	**Identical**
Intended Use Environment	Intended for use in hospitals, outpatient nursing units and other suitable clinical environments	Intended for use in hospitals, outpatient nursing units and other suitable clinical environments	**Identical**
Device Product Code, Class & Classification Name	LHI, Class II, I.V. Fluid Transfer Set	LHI, Class II, I.V. Fluid Transfer Set	**Identical**
Regulation Number / Name	21CFR 880.5440 Intravascular Administration Set	21CFR 880.5440	**Identical**

Areas for Comparison	Subject Device Vial2Bag Advanced® 13mm Admixture Device	Predicate Device (K201415): Vial2Bag Advanced® 20mm Admixture Device	Comparison
		Intravascular Administration Set	
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**
Design			
Operation Principle	Manual	Manual	**Identical**
Design	Made of plastic material, featuring a 13mm Vial Adaptor to access the drug content in the 13mm vial, an IV Spike integrated for the connection to the IV bag, and a twist off which after removal opens the IV port for connection to the IV administration set.	Made of plastic material featuring a 20mm Vial Adaptor to access the drug content in the 20mm vial, an IV Spike integrated for the connection to the IV bag, and a twist off which after removal opens the IV port for connection to the IV administration set.	**Difference #2–** Performance, chemical and biocompatibility testing confirmed material and vial adapter size do not impact device intended use, clinical effectiveness, or safety profile.
Materials of Construction	• 13mm Vial Adapter: Polycarbonate (PC) + Orange colorant masterbatch	• 20mm Vial Adapter: PC + Blue colorant masterbatch	**Difference #3 –** Performance, chemical and biocompatibility testing confirmed differences in colorant do not impact device intended use, clinical effectiveness, or safety profile.
	• IV Port Twist Off: PC + Polyvinyl Chloride (PVC) 3224	• IV Port Twist Off: PC + Polyvinyl Chloride (PVC) 3250	**Difference #3 –** Polycarbonate is identical, differs in PVC. Performance, chemical and biocompatibility testing confirmed differences in PVC grade do not impact device intended use, clinical effectiveness, or safety profile.
	• Spike Protector: Low Density Polyethylene (LDPE)	• Spike Protector: LDPE	**Identical**
Compatible Vial Size	13mm	20mm	**Difference #2–** Performance testing confirmed differences noted with compatible vial size do not impact device intended use, clinical effectiveness, or safety profile.

Areas for Comparison	Subject Device Vial2Bag Advanced® 13mm Admixture Device	Predicate Device (K201415): Vial2Bag Advanced® 20mm Admixture Device	Comparison
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**
Vial Adapter Fit	Vial first, snap fit to vial	Vial first, snap fit to vial	**Identical**
Performance on fluid transfer	Transfer of vial contents to the IV bag and to the administration set was quantified to establish product requirement for the subject device.	Subject device can transfer equivalent vial contents to the IV bag and administration set compared with the predicate device.	**Identical**
Biocompatibility	ISO 10993-1:2018 External Communicating, Prolonged Indirect Blood Contact (>24hr to 30 days)	ISO 10993-1:2018 External Communicating, Prolonged Indirect Blood Contact (>24hr to 30 days)	**Identical**
Non-pyrogenic	Yes	Yes	**Identical**
Sterilization			
Sterility	Sterile	Sterile	**Identical**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Identical**
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	**Identical**
Packaging			
Packaging	Sterile Barrier package materials: PETG blister with Tyvek® seal	Sterile Barrier package materials: PETG blister with Tyvek® seal	**Identical**

The results of performance, biocompatibility, and human factors studies for the subject device, provided within this submission, demonstrate that the differences between the subject device and the predicate device do not raise any additional concerns regarding risk, safety, and effectiveness. See details as follows:

- **Difference #1 –** Human Factors (Section 8.1), Performance (Table 7-1) and Biocompatibility (Section 7.3) testing confirmed the differences in indications for use, including the subject device accommodating a smaller 13mm drug vial size and the adolescent and adult patient population do not raise new or additional concerns regarding device safety profile or clinical effectiveness.

- **Difference #2 –** Performance (Table 7-1), chemical (Section 7.2) and biocompatibility (Section 7.3) testing confirmed differences in design and compatible vial size do not impact device intended use, clinical effectiveness, or safety profile.

- **Difference #3 –** Performance (Table 7-1), chemical (Section 7.2) and biocompatibility (Section 7.3) testing confirmed differences in materials of construction do not impact device intended use, clinical effectiveness, or safety profile.

For the reasons listed above, the Vial2Bag Advanced® 13mm Admixture Device, subject of this Traditional 510(k), is substantially equivalent in its intended use, design/construction, technology/principle of operation, materials, and performance to the predicate device, Vial2Bag Advanced 20mm Admixture Device, which is cleared under K201415.

7 PERFORMANCE DATA

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

7.1 Performance Testing

Performance testing was conducted to ensure that the Vial2Bag Advanced® 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. The table below provides a list of non-clinical bench performance tests that were completed on the device and provided within this submission.

Table 7-1: Summary of Performance Testing

Test	Test Method/ Standard
Dose Concentration of Delivery Profile	In-house test methods
Twist Off Opening Torque from IV Port	In-house test method
Vial Adaptor Tensile Detachment Force	In-house test method
Vial Adaptor Torque Test	In-house test method
Vial Adapter to Vial Penetration Force	In-house test method
Detachment Force of Vial Adapter from Vial	In-house test method
Visual Inspection for Product Damage	In-house test method
Leakage test (Device)	ISO-8536-4; Section 7.2
Internal Diameter of the Upper Skirt for Vial Adapter	In-house test method
1m Drop Durability	In-house test method
IV Port Tensile Strength	ISO 8536-4; Section 7.3

Test	Test Method/ Standard
IV Spike to IV Port Attachment Force	In-house test method
Leakage test (IV spike to IV port)	In-house test method
IV Spike from IV Port Detachment Force	ISO 8536-4 Section 7.3
IV Spike Dimensions	ISO 8536-4:2019; Section 7.4
Flow rate	ISO 8536-4:2019; Section 7.10
IV Spike Protector Detachment Force	ISO 8536-4:2019; Section 7.13
Visual Inspection of Device	In-house test method
Finger Flange Break Force	In-house test method
Short Circuit Test Method	In-house test method
IV Spike Lumen Dimensions	In-house test method
Particulate	USP <788>
Fragmentation	Acceptance criteria based on EN ISO 8536-2, section 6.2.2 and sample size based on EN ISO 7864, Annex B, Section B.4.
Mass Transfer	In- house test method
Residual Volume	In-house test method
Coring	Acceptance criteria based on EN ISO 8536-2, section 6.2.2 and sample size based on EN ISO 7864, Annex B, Section B.4.

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, the objective evidence satisfies the product requirements for performance, safety, and effectiveness and the results support a determination of substantial equivalence.

7.2 Chemical Tests

To assure the device can properly serve as a connection between IV bags and Administration Sets, Vial2Bag Advanced 13mm Admixture Devices were tested to ISO 8536-4: 2019 *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*; Annex B. The test results provide evidence that the device meets the requirements listed in ISO 8536-4:2019*,* Annex B Chemical Tests.

7.3 Biocompatibility Testing

In accordance with ISO 10993-1: 2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, the subject Vial2Bag Advanced 13mm 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 2023 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 have been successfully conducted on the Vial2Bag Advanced 13mm Admixture Device:

Cytotoxicity (Tested to ISO 10993-5: 2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*)

Sensitization (Tested to ISO 10993-10: 2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*)

Intracutaneous Reactivity (Tested to ISO 10993-10: 2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*)

Acute Systemic Toxicity (Tested to ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*)

Material Mediated Pyrogenicity (Tested to ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*)

Systemic (Subacute) Toxicity (Tested to ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*)

Hemolysis (Tested to ISO 10993-4: 2017 *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood* and ASTM F756-17 *Standard Practice for Assessment of Hemolytic Properties of Materials*)

Based upon the results of the biocompatibility tests, the materials used to manufacture the subject device are considered biocompatible. The biocompatibility results demonstrate the subject device does not raise any additional concerns regarding risk, safety, and effectiveness; therefore, the subject Vial2Bag Advanced 13mm Admixture Device is considered substantially equivalent to the predicate device.

7.4 Sterilization

The sterility of the subject device is assured using a sterilization method validated in accordance with ISO 11135:2014/AMD1:2018 *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*. The sterilization method provides a sterility assurance level (SAL) of 10^{-6}.

8 CLINICAL DATA

No clinical trial was performed for Vial2Bag Advanced 13mm Admixture Device.

8.1 Human Factors

A Human Factors Validation study was conducted to demonstrate that intended users are able to use the device safely and effectively without patterns of preventable use errors, or difficulties that could result in serious harm to the user or patient.

The subject device related IFU was validated in simulated use sessions with representatives of the intended user groups to establish safe and effective preparation for drug administration by healthcare professionals. An evaluation of the subject device Blister Pack, Carton, and associated labeling were also included.

There were no repeatable patterns of use-related errors resulting in failures, close calls, operational difficulties, or foreseeable misuse of the Vial2Bag Advanced® 13mm admixture device. This Human Factors study validated that recruited nurses, physicians, and pharmacists can operate the subject device safely and effectively per the intended use. The results of this study provided objective evidence and determined that the potential use errors identified in the use-related risk analysis that could lead to serious harm have been mitigated to acceptable levels. All risk control measures were found to be effective.

9 CONCLUSION

In summary, the Vial2Bag Advanced® 13mm Admixture Device, the subject of this Pre-market Notification, is as safe, as effective, and is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate device, Vial2Bag Advanced 20mm Admixture Device (K201415).