May 3, 2024

West Pharmaceutical Services, Inc.
% Fred Cowdery
Director Regulatory Affairs
530 Herman O. West Drive
Exton, Pennsylvania 19431

Re: K240940
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: March 19, 2024
Received: April 5, 2024

Dear Fred Cowdery:

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,
Porsche Bennett
Porsche Bennett
For 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

Enclosure

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)*
K240940

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. 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.

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

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K240940 - 510(K) SUMMARY

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: 05-Apr-2024

DEVICE

Trade Name:	Vial2Bag Advanced® 20mm 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

PREDICATE DEVICE

Vial2Bag Advanced® 13mm Admixture Device (K230988).

A reference device, Vial2Bag Advanced® 20mm Admixture Device; K201415 is also included in this submission.

DEVICE DESCRIPTION

Device Design and Operation

The Vial2Bag Advanced® 20mm Admixture Device is a single-use, sterile, needle-less, nonpyrogenic, 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 intended to be used with standard drug vials with a 20mm closure and an elastomeric stopper. The Vial2Bag Advanced® 20mm 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 no additional accessories are required nor provided with the Vial2Bag Advanced® 20mm 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 the patient.

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. Indicated for adolescent and adult patients only.

Both the subject and predicate devices have the same intended use except for the specified vial closure diameter. While the predicate device is intended to interface with vials having a 13mm closure, the subject device is intended to interface with vials having a 20mm closure.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALAENCE

The Vial2Bag Advanced® 20mm Admixture Device, subject of this Special 510(k), is substantially equivalent in its intended use, design, technology, principles of operation, materials (with exception of Vial Adapter colorant additive), and performance to the predicate device, Vial2Bag Advanced® 13mm Admixture Device, cleared under K230988.

A summary comparing the subject device and the predicate device are provided in the table below.

Substantial Equivalence Comparison Table

Areas for Comparison	**Subject Device** Vial2Bag Advanced® 20mm Admixture Device	**Predicate Device (K230988)** Vial2Bag Advanced® 13mm Admixture Device	**Comparison**
Indications for Use	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. Indicated for adolescent and adult patients only.	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.	**Difference #1:** Although the subject device Vial Adapter size differs from the predicate device, the reference device performance test results confirm the vial adapter size does not raise new or different questions of safety and 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 Intravascular Administration Set	**Identical**
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**
Operation Principle	Manual	Manual	**Identical**
Design	Made of plastic material, featuring a Vial Adaptor to access the drug content	Made of plastic material, featuring a Vial Adaptor to access the drug content in a	**Difference #1:** Although the subject device Vial Adapter size differs from

Areas for Comparison	**Subject Device** Vial2Bag Advanced® 20mm Admixture Device	**Predicate Device (K230988)** Vial2Bag Advanced® 13mm Admixture Device	**Comparison**
	in a 20mm vial, an IV Spike integrated for connection to an IV bag, and a twist off which, after removal, opens the IV port for connection to the IV administration set.	13mm vial, an IV Spike integrated for connection to an IV bag, and a twist off which, after removal, opens the IV port for connection to the IV administration set.	the predicate device, the reference device performance test results confirm the vial adapter size difference does not raise new or different questions of safety and effectiveness.
Materials of Construction	20mm Vial Adapter: Polycarbonate (PC) + Blue colorant masterbatch	13mm Vial Adapter: Polycarbonate (PC) + Orange colorant masterbatch	**Difference #2:** Although the subject device Vial Adapter colorant differs from the predicate device, the reference device Biocompatibility test reports confirm subject device colorant does not impact device intended use, clinical effectiveness, or safety profile.
	IV Port Twist Off: PC + Polyvinyl Chloride (PVC) 3224 (non-DEHP)	IV Port Twist Off: PC + Polyvinyl Chloride (PVC) 3224 (non-DEHP)	**Identical**
	Spike Protector: Low Density Polyethylene (LDPE)	Spike Protector: Low Density Polyethylene (LDPE)	**Identical**
Compatible Vial Size	20mm	13mm	**Difference #1:** Although the subject device Vial Adapter size differs from the predicate device, the reference device performance test results confirm the vial adapter size does not raise new or different questions of safety and effectiveness.
Bag Size	50, 100, 250mL	50, 100, 250mL	**Identical**
Dose Concentration	200%	200%	**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.	Transfer of vial contents to the IV bag and to the administration set was quantified to establish product requirement.	**Identical**
Biocompatibility	ISO 10993-1:2018 External Communicating, Prolonged Indirect Blood	ISO 10993-1:2018 External Communicating, Prolonged Indirect Blood Contact (>24hr to 30 days)	**Identical**

Areas for Comparison	**Subject Device** Vial2Bag Advanced® 20mm Admixture Device	**Predicate Device (K230988)** Vial2Bag Advanced® 13mm Admixture Device	**Comparison**
	Contact (>24hr to 30 days)		
Non-pyrogenic	Yes	Yes	**Identical**
Sterility	Sterile	Sterile	**Identical**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Identical**
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	**Identical**
Packaging	Sterile Barrier package materials: PETG blister with Tyvek® seal	Sterile Barrier package materials: PETG blister with Tyvek® seal	**Identical**

- **Difference #1–** Although the subject device Vial Adapter size differs from the predicate device, the reference device, performance test results confirm the vial adapter size does not raise new or different questions of safety and effectiveness.

- **Difference #2 -** Although the subject device Vial Adapter colorant differs from the predicate device, the reference device Biocompatibility and Chemical test reports confirm subject device colorant does not impact device intended use, clinical effectiveness, or safety profile.

Although the subject and reference devices are similar in design and technology, the reference device materials contain a DEHP plasticizer additive, which is not present in the subject device components. Functionally, the subject device, Vial2Bag Advanced® 20mm Admixture Device, is otherwise the same as the reference device cleared under K201415.

PERFORMANCE DATA

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.

Risks associated with the proposed changes to the subject device do not alter or introduce new device risks. The Risk Management Files prepared for both the predicate and reference devices have been maintained and remain applicable to the subject device.

This change does not raise new or different questions of safety and effectiveness. Therefore, the subject device is as safe and effective as the predicate device.

Summary of Performance Testing

Test	Test Method/ Standard
Vial Adaptor Tensile Detachment Force	In-house test method
Vial Adaptor Torque Test	In-house test method
Detachment Force of Vial Adapter from Vial	In-house test method
Attachment Force of Vial Adapter to the Vial	In-house test method
Leakage Testing	In-house test method
Internal Diameter of the Upper Skirt for Vial Adapter	In-house test method
1m Drop Durability	In-house test method
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
Dose Concentration	In-house test method

Biocompatibility Testing

In accordance with ISO 10993-1, the subject device, 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 subject device materials are identical to materials included in the predicate device submission (K230988), except for the vial adapter component colorant additive. While the predicate device contains an orange colorant, the subject device contains a blue colorant identical to the reference device colorant.

Since the subject device vial adapter colorant is identical to the colorant used in the reference device vial adapter component, the reference device (K201415) biocompatibility test reports are deemed applicable and are being leveraged for the subject device to demonstrate the subject device biological safety.

CLINICAL DATA

No clinical trial was performed for the subject device, Vial2Bag Advanced® 20mm Admixture Device, nor required to support the proposed changes.

CONCLUSION

In summary, the Vial2Bag Advanced® 20mm Admixture Device, the subject of this Premarket Notification, is as safe, as effective, and is substantially equivalent in its intended use, technology/principle of operation, and performance to the predicate device, Vial2Bag Advanced® 13mm Admixture Device (K230988).