January 19, 2024

% Lauren Tiller
Senior Regulatory Affairs Specialist
West Pharmaceutical Services, Inc.
530 Hermon O. West Drive
Exton, Pennsylvania 19341

Re: K231071
Trade/Device Name: Mix2Vial® Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: December 21, 2023
Received: December 21, 2023

Dear Lauren Tiller:

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)*
K231071

Device Name
Mix2Vial® Transfer Device

Indications for Use *(Describe)*
The Mix2Vial® Transfer Device is intended for transferring drugs contained in two vials.

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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K231071 - 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.
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Facility Establishment Registration Number: 3000223297

Applicant & Correspondent Contact Person:

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Date Prepared: January 19, 2024

DEVICE

Trade Name: Mix2Vial® Transfer 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: Mix2vial Transfer Device – K031861

DEVICE DESCRIPTION

Device Overview

The subject device, Mix2Vial® Transfer Device (M2V), is a single-use, gamma sterilized, non-pyrogenic device intended for the transfer of drugs contained in two vials. The M2V consists of two vial adapter bodies with piercing spike and wings, connected back-to-back via a Luer connection, with an in-line filter.

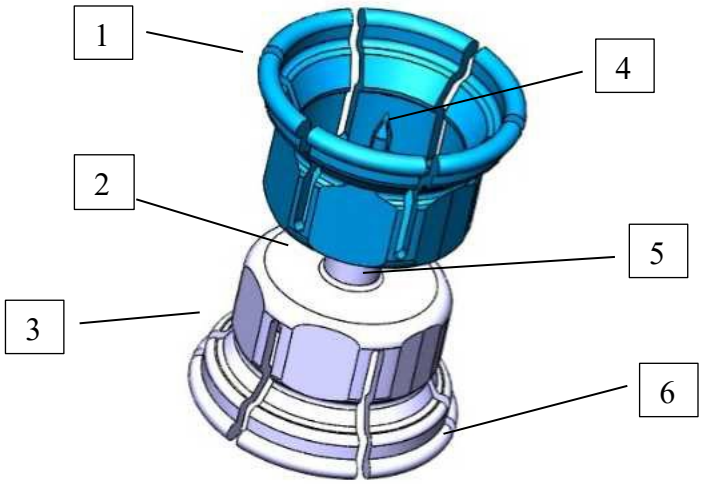
The female vial adapter (clear) connects to the drug vial and the male vial adapter (blue) connects to the diluent vial. The vacuum present in the lyophilized drug vial draws in the contents of the diluent vial.

The female Luer connection interfaces to a syringe and has an in-line 5µm filter that strains the drug or solution when aspirated out of the vial. The male connection has a "Tight Grip" that provides a secure connection to the diluent vial having a 20mm neck diameter.

Puncturing the elastomeric closure or "stopper" of a drug or diluent vial is achieved by means of an integral polycarbonate cannulated spike located in the center of each Vial Adapter (VA) body of the M2V. Each side of the device (diluent vial side and drug vial side) is a polycarbonate molded part containing a Luer port.

After reconstitution, the drug can be administered by disconnecting the diluent vial and connecting a needleless syringe to the female Luer Lock of the female Vial Adapter. The device does not contain any medicinal substances and can be used with drug vials/diluent vials with a neck diameter of 20mm. The figure below depicts the components of the device.

Mix2Vial® Transfer Device



1. Male Vial Adapter Component (VA)
2. In-line Filter (inside Female VA)
3. Female VA
4. Spike
5. Luer Connector
6. Skirt Wings

The M2V has a 5-year shelf life.

The M2V device is intended for use by a patient (adolescents and adults) or caregivers for Home Use (HU) and by Healthcare Professionals (HCPs) in a clinical, hospital, or other healthcare environment. The subject device is available by prescription use only and has no known contraindications.

The M2V primary packaging consists of a polyethylene terephthalate glycol (PETG) blister that is sealed with a Tyvek® lid on top of the blister pack.

Principle of Operation

The M2V is operated by a manual process. The device is connected to a diluent vial (supplied by the Drug Manufacturer) having a neck diameter of 20mm via the male Vial Adapter portion of the device. Then, the device is connected to a drug vial (supplied by the Drug Manufacturer) having a neck diameter of 20mm via the female Vial Adapter portion of the device.

The vial adapters contain an integral plastic cannulated spike located in the center of the Vial Adapter components, intended to puncture the vial stopper membrane allowing access to the vial contents. This piercing cannulated spike then facilitates the transfer of the drug between the diluent vial and the drug vial.

The device is swirled to mix the drug per the Drug Manufacturer's package insert.

The male Vial Adapter (with diluent bottle still attached) is unscrewed from the female Vial Adapter and discarded.

An empty syringe is pressurized then connected to the female Luer Lock (port on female Adapter). Once connection is secure, the air from the syringe is injected into the vial.

The device is then flipped, and the plunger of the syringe is pulled downward to withdraw the desired amount of the reconstituted drug. The device is flipped back with the vial side down, and the syringe is removed.

The drug can now be administered through the syringe.

INDICATION FOR USE

The Mix2Vial® Transfer Device is intended for transferring drugs contained in two vials.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Mix2Vial® Transfer Device is substantially equivalent in its intended use, design/construction, technology/principle of operation, materials, and performance to the predicate device Mix2vial Transfer Device, cleared under K031861.

A summary of equivalence and differences between the subject device and the predicate device are provided in the table below.

Substantial Equivalence Comparison Table

Areas for Comparison	Subject Device Mix2Vial® Transfer Device	Predicate Device (K031861) Mix2vial Transfer Device	Comparison
General Information			
Indications for Use	Transferring drugs contained in two vials	Transferring and mixing of drugs contained in two vials	**Difference #1:** The subject device has had a reduction of "mixing" from the indications for use.
Contraindications	None known	None known	**Identical**
Intended User Population	Intended for use by patients (adolescents and adults), caregivers, and by Healthcare Professionals (HCPs)	Intended for use by Healthcare Professionals (HCPs)	**Difference #2:** The subject device is intended to be used by Healthcare Professionals (HCPs) and by patients / lay users (adolescents and adults) and caregivers for Home Use.

Areas for Comparison	Subject Device Mix2Vial® Transfer Device	Predicate Device (K031861) Mix2vial Transfer Device	Comparison
Intended Use Environment	Intended for Home Use and in hospitals, outpatient nursing units and other suitable clinical environments	Intended for use in hospitals, outpatient nursing units and other suitable clinical environments	**Difference #3:** The subject device is intended to be used for Home Use and in hospitals, outpatient nursing units and other suitable clinical environments.
Device Class & Classification Name	Class II, I.V. Fluid Transfer Set	Class II, I.V. Fluid Transfer Set	**Identical**
Regulation Number / Name	21CFR 880.5440 Intravascular Administration Set	21CFR 880.5440 Intravascular Administration Set	**Identical**
Product Code	LHI	LHI	**Identical**
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**
Shelf life	5 years	5 years	**Identical**
Design			
Operation Principle	Manual	Manual	**Identical**
Direction of Flow	Two-way	Two-way	**Identical**
Design/ Construction	Female 20mm Vial Adapter with wings and piercing short spike, containing an in-line filter intended to be attached to a standard drug vial with a neck diameter of 20mm. Female Luer Lock fitting is compliant with ISO 80369-7 for attachment to a standard accessory such as a syringe (not supplied). Male 20mm Vial Adapter with "tight grip" wings and piercing short spike intended to be attached to a standard diluent vial with a neck diameter of 20mm.	Female 20mm Vial Adapter with wings and piercing spike, containing an in-line filter intended to be attached to a standard drug vial with a neck diameter of 20mm. Female Luer Lock fitting is compliant with ISO 594-1 and ISO 594-2 for attachment to a standard accessory such as a syringe (not supplied). Male 20mm Vial Adapter with wings and piercing spike intended to be attached to a standard diluent vial with a neck diameter of 20mm.	**Difference #4:** The subject device female vial adapter is compliant with ISO 80369-7, both vial adapters have a 1.5mm shorter spike, and the male vial adapter has "tight grip" wings.
Female Luer Lock Connector	Compliant with ISO 80369-7:2021	Compliant with ISO 594-1 and ISO 594-2	**Difference #5:** The subject device complies with the most current Luer standard revision.
Compatible Vial Size	20mm	20mm	**Identical**

Areas for Comparison	Subject Device Mix2Vial® Transfer Device	Predicate Device (K031861) Mix2vial Transfer Device	Comparison
Female Vial Adapter Wing Diameter	30.4mm to accommodate 20mm standard vials	30.4mm to accommodate 20mm standard vials	**Identical**
Male Vial Adapter Wing Diameter	30.1mm to accommodate 20mm standard vials	30.4mm to accommodate 20mm standard vials	**Difference #6:** The male vial adapter of the subject device has a Tight Grip (TG) 30.1mm external body diameter, a .3mm reduction.
Piercing Spike	Single lumen 11.25mm short spike	Single lumen 12.75mm standard spike	**Difference #7:** The subject device has a 11.25mm short spike, a 1.5mm reduction.
Vial Adapter Fit	Snap fit to vial	Snap fit to vial	**Identical**
Material	Vial Adapters: Polycarbonate In-Filter: Polyethylene + Hydrophilic Mesh	Vial Adapters: Polycarbonate In-Filter: Polyethylene + Hydrophilic Mesh	**Identical**
Biocompatibility	ISO 10993-1:2018 External Communicating, Prolonged Indirect Contact with Patient Blood Path (24 hours to 30 days)	USP Biological Reactivity External Communicating, Transient Indirect Contact with Patient Blood Path (≤ 24 hours)	**Difference #8:** The subject device is compliant with the latest biocompatibility standard and has Prolonged Indirect Contact with Patient Blood Path (24 hours to 30 days).
Non-pyrogenic	Yes	Yes	**Identical**
Sterilization			
Sterility	Sterile	Sterile	**Identical**
Sterilization Method	Gamma	Gamma or ETO	**Difference #9:** The subject device is gamma sterilized.
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 sterility testing for the subject device, demonstrate that the differences between the subject device and the predicate device do not raise new or different questions of safety and effectiveness. See details as follows:

- **Difference #1:** The "mixing" claim has been removed from the device labeling, including the Indications for Use statement as the drug mixing requirements are defined by the Drug

Manufacturer, as indicated in the device Instructions for Use. Therefore, West Pharmaceutical Services, Inc does not maintain verification or validation data within the device Design History File to substantiate the mixing claim.

This change does not raise new or different questions of safety and effectiveness.

- **Difference #2:** The subject device is intended to be used by Healthcare Professionals (HCPs) which is identical to the predicate; however, the subject device is also intended for use by patients / lay users (adolescents and adults) and caregivers for Home Use. This change does not raise new or different questions of safety and effectiveness.
- **Difference #3:** The subject device is intended to be used in hospitals, outpatient nursing units, and other suitable clinical environments, identical to the predicate; however, the subject device is also intended for Home Use. This change does not raise new or different questions of safety and effectiveness.
- **Difference #4:** The subject device female vial adapter is compliant with ISO 80369-7, both vial adapters have a 1.5mm shorter spike, and the male vial adapter has "tight grip" wings. The predicate device Luer fitting is compliant with ISO 594-1 and ISO 594-2. Both ISO 594-1 and ISO 594-2 were superseded with ISO 80369-7.

  This change does not raise new or different questions of safety and effectiveness.
- **Difference #5:** The subject device complies with the most current Luer standard revision. This change does not raise new or different questions of safety and effectiveness, as demonstrated by bench testing.
- **Difference #6:** The subject device male Vial Adapter has "Tight Grip" which is a .3mm diameter reduction from the predicate, while still accommodating a standard 20mm drug vial. This change does not raise new or different questions of safety and effectiveness, as demonstrated by bench testing.
- **Difference #7:** The subject device has 11.25mm "short spikes," which is a 1.5mm reduction from the predicate. This change does not raise new or different questions of safety and effectiveness, as demonstrated by bench testing.
- **Difference #8:** The subject device contact duration has been extended to prolonged (24 hours to 30 days) and complies with the most current biocompatibility standards. This change does not raise new or different questions of safety and effectiveness, as demonstrated by biocompatibility testing.
- **Difference #9:** The subject device is only sterilized by Gamma Irradiation, while the predicate device had the option to be either EtO or Gamma sterilized. This change does not raise new or different questions of safety and effectiveness, as demonstrated by sterilization validation.

For these reasons, the Mix2Vial® Transfer 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, Mix2vial Transfer Device, which is cleared under K031861.

PERFORMANCE DATA

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

Performance Testing

Performance testing was conducted to confirm the Mix2Vial® Transfer Device meets all applicable design and performance requirements throughout its defined shelf life, conforms to the applicable external and internal standards, and demonstrates 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.

Summary of Performance Testing

Test	Test Method/ Standard
Fragmentation Test	ISO 8536-2:2010 section 6.2.2
Particulate Testing	USP <788>
Internal Diameter Upper Skirt	ISO 8362-6:2010 Section 4.2
Luer Gauging Test	ISO 594-1:1986 and ISO 594-2:1998
Luer Stability and compliance to ISO 80369-7	ISO 80369-7:2021
Luer Stability and compliance to ISO 80369-7	ISO 80369-20:2015, Annex B & Annex C for the leakage reference connector (fluid leakage)
Luer Stability and compliance to ISO 80369-7	ISO 80369-20:2015, Annex D & Annex C for the leakage reference connector (air leakage)
Luer Stability and compliance to ISO 80369-7	ISO 80369-20: 2015, Annex E & Annex C for the stress cracking reference connector
Luer Stability and compliance to ISO 80369-7	ISO 80369-20: 2015, Annex F & Annex C for the axial load reference connector
Luer Stability and compliance to ISO 80369-7	ISO 80369-20: 2015, Annex G & Annex C for the resistance separation from unscrewing reference connector
Luer Stability and compliance to ISO 80369-7	ISO 80369-20: 2015, Annex G & Annex C for the overriding reference connector
Luer Stability and compliance to ISO 80369-7	ISO 80369-7:2021 Table B.2 and B.5 (compliance to dimensions)

Test	Test Method/ Standard
Residual Volume	In-house test method
Device Leakage	In-house test method
Device Total Penetration Force	In-house test method
Vial Adapter Detachment Force	In-house test method
Product Retention in Blister	In-house test method
Vacuum Test	In-house test method
Device Removal Force from Blister	In-house test method
Tyvek Total Peel Test Force	In-house test method
Functionality according to IFU	In-house test method
Leakage under Normal Use	In-house test method
Product Skirt Position on Vial	In-house test method
Injection Force	In-house test method
Aspiration Force	In-house test method
Label Legibility	In-house test method
Opening Torque Test	In-house test method

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 for performance, safety, and effectiveness, and the results support a determination of substantial equivalence to the predicate device.

Biocompatibility Testing

The biocompatibility evaluation for the Mix2Vial® Transfer Device was conducted in accordance with, 2020 FDA Guidance: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.* and International Standard *ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,*" as recognized by FDA.

In accordance with ISO 10993-1:2018, the subject device Mix2Vial® Transfer Device is classified as an externally communicating device, having prolonged indirect contact with the patient blood path (24 hours to 30 days).

Sterilization

The subject device is terminally sterilized using a Gamma irradiation sterilization method, validated in accordance with standard *BS EN ISO 11137-1:2015 & A2:2019 Sterilization of health care products – Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and *BS EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose, and ISO 13004 - Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose: Method $VD_{max}SD$*. The sterilization method of Gamma irradiation provides a sterility assurance level (SAL) of 10^{-6}.

Bacterial Endotoxin Testing by limulus amebocyte lysate (LAL) was also performed on the same batch of product used for sterility dose verification, which passed with acceptable levels, further ensuring the safety of the device.

CLINICAL DATA

Clinical trials were not performed for the Mix2Vial® Transfer Device.

CONCLUSION

In summary, the subject device, Mix2Vial® Transfer Device is determined to be substantially equivalent to the predicate device (K031861) in technology, principle of operation, materials, and performance in comparison to the predicate device, when used as intended in the intended use environment by the intended users.