May 23, 2023

West Pharma Services IL, Ltd.
% Fred Cowdery
Director, Regulatory Affairs
West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, Pennsylvania 19341

Re: K230464
Trade/Device Name: MixJect® Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI

Dear Fred Cowdery:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 22, 2023. Specifically, FDA is updating this SE Letter to add the missing clearance date as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Wolloscheck, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 301-796-1480, david.wolloscheck@fda.hhs.gov.

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

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Re: K230464
Trade/Device Name: MixJect® Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: February 17, 2023
Received: February 21, 2023

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 (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,

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230464

Device Name
MixJect® Transfer Device

Indications for Use *(Describe)*
The device is intended for the transfer and injection of drugs contained in a vial.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K230464 - 510(k) SUMMARY

Date Prepared: May 22, 2023

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:

Fred Cowdery
Director, Regulatory Affairs, Medical Devices
Phone: 267-205-1273
Fax: 610-717-0668
E-mail: fred.cowdery@westpharma.com

SUBJECT DEVICE

Trade Name:	MixJect® 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

Predicate Device	MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle
510(k) Number	K001293
Common/Usual Name	I.V. Fluid Transfer Set
Product Code	LHI

Regulation Name / Number / Class	Intravascular Administration Set / 21CFR880.5440 / Class II
Panel	General Hospital

INDICATION FOR USE

The device is intended for the transfer and injection of drugs contained in a vial.

DEVICE DESCRIPTION

Device Overview

The subject device, MixJect® Transfer Device (MXJ), is a single-use, gamma sterilized, non-pyrogenic device intended for the transfer and injection of drugs contained in a vial.

The MXJ device is intended for use 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 MXJ device does not contain any medicinal substances and is only intended for use with drug vials having a neck diameter of 13mm. The subject device has a 3-year shelf life.

The MXJ device configuration consists of four main components inclusive of a 30-gauge needle, a vial adapter including integral cannulated spike, MXJ Body, and MXJ Core.

The subject device interfaces with a syringe (not supplied) that connects to the female Luer lock port located in the main body of the MXJ device.

The MXJ Vial Adapter component connects to a drug vial having a neck diameter of 13mm. The Vial Adapter component contains a piercing spike and a female Luer lock connector. Puncturing of the drug vial stopper membrane is achieved by means of an integral spike located in the center of the MXJ Vial Adapter component. Once the drug vial stopper membrane is breached by the cannulated spike, fluid can travel from the drug vial into the MXJ device main body.

A prefilled diluent syringe (not supplied) is then connected to MXJ female Luer lock port. The diluent is injected from the syringe into the drug vial. The reconstituted medicament is then aspirated back into the syringe. The MXJ device is then twisted in a counterclockwise direction, changing the fluid path from the syringe-vial to the syringe-needle. After reconstitution and aspiration, the drug is ready to be administered through the attached MXJ needle.

The MXJ primary device package consists of a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek® lid sealed on top of the blister pack.

In accordance with ISO 10993-1:2018, the subject device MixJect® Transfer Device is classified as an externally communicating device, having limited indirect contact with the patient blood path (< 24 hour). The subject device needle has transient contact (<60 minutes) with the patient body.

Principle of Operation

The MXJ is operated by a manual process. The subject device connects to a drug vial (supplied by the Drug Manufacturer) having a neck diameter of 13mm via the Vial Adapter portion of the MXJ device.

The vial adapter contains an integral plastic cannulated spike located in the center of the MXJ Vial Adapter component, 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 vial and the syringe.

A prefilled diluent syringe is then connected to the MXJ, interfacing to a female Luer lock port located on the MXJ body.

The diluent is then injected into the drug vial. The reconstituted medicament is then aspirated back into the syringe.

The MXJ body is then manually rotated in a counterclockwise direction, changing the fluid path from the syringe-vial to the syringe-needle.

After reconstitution and aspiration, the drug can be administered through the attached syringe / needle.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The MixJect® Transfer Device is substantially equivalent in its intended use, design/construction, technology/principle of operation, materials, and performance to the predicate device, MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle, cleared under K001293.

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** MixJect® Transfer Device	**Predicate Device (K001293):** MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle	**Comparison**
General Information			
Manufacturer	West Pharma. Services IL, Ltd.	Medimop Medical Projects, Ltd./West Pharma. Services IL., Ltd.	**Different;** Medimop acquired by West Pharmaceutical Services, Inc.
Device Trade Name	MixJect® Transfer Device	MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle	**Similar:** Changed for marketing purposes only. Change does not impact device intended use.
Catalog Number	970133	800405	**Similar:** Change does not impact device intended use.
Indications for Use	The MixJect® Transfer Device is intended for the transfer and injection of drugs contained in a vial.	Transfer, mixing, and injection of drugs contained in a vial.	**Similar –** Differences 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 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**

Areas for Comparison	**Subject Device** MixJect® Transfer Device	**Predicate Device (K001293):** MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle	**Comparison**
Product Code	LHI	LHI	**Identical**
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**
Shelf life	3 years	3 years	**Identical**
Design			
Operation Principle	Manual	Manual	**Identical**
Design/construction	Featuring a 13mm Vial Adaptor body with tight grip hold ("wings"), intended to be attached to a standard drug vial with a neck diameter of 13mm. The device contains a piercing spike, a 30Ga Needle and a female Luer lock fitting compliant with BS EN ISO 80369-7:2016, for attachment to a standard accessory such as a syringe (not supplied).	Featuring a 13mm Vial Adaptor body with tight grip hold ("wings"), intended to be attached to a standard drug vial with a neck diameter of 13mm. The device contains a piercing spike, a 30Ga Needle and a female Luer lock fitting compliant with ISO 594-1 and ISO 594-2, for attachment to a standard accessory such as a syringe (not supplied).	**Similar –** Differences noted with ISO Luer Standard compliance do not alter device intended use, clinical effectiveness, or safety profile.
Female Luer Lock Connector	Compliant with BS EN ISO 80369-7:2016	Compliant with ISO 594-1 and ISO 594-2	**Similar –** Subject device updated for compliance with latest ISO Luer standard. No change in intended use.
Compatible Vial Size	13mm	13mm	**Identical**
Body Diameter	18.5mm to accommodate 13mm standard vials.	18.5mm to accommodate 13mm standard vials.	**Identical**
Piercing Spike	Single lumen	Single lumen	**Identical**
Vial Adapter Fit	Vial first, snap fit to vial	Vial first, snap fit to vial	**Identical**
Material	MixJect Body: Polycarbonate MixJect Core: High Density Polyethylene MixJect Vial Adapter Body: Polycarbonate	MixJect Body: Polycarbonate MixJect Core: High Density Polyethylene MixJect Vial Adapter Body: Polycarbonate	**Identical**

Areas for Comparison	Subject Device MixJect® Transfer Device	Predicate Device (K001293): MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle	Comparison
Biocompatibility	ISO 10993-1:2018 External Communicating, Transient Contact (<60 min)	ISO 10993-1 and USP Biological Reactivity External Communicating, Transient Contact (<60 min)	**Identical**
Non-pyrogenic	Yes	Yes	**Identical**
Sterilization			
Sterility	Sterile	Sterile	**Identical**
Sterilization Method	Gamma	Gamma	**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 orientation: Devices are supplied in an individual blister, vial first orientation.	Sterile Barrier package materials: PETG blister with Tyvek® seal Sterile Barrier package orientation: Devices are supplied in an individual blister, vial first orientation.	**Identical**

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 MixJect® Transfer Device meets all applicable design and performance requirements throughout its defined shelf life and 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.

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)
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
Flow Rate	In-house test method
Device Removal Force from Blister	In-house test method
Tyvek Total Peel Test Force	In-house test method

Test	Test Method/ Standard
Internal Diameter Dimensional Measurements Upper Skirt	In-house test method
Functionality according to IFU	In-house test method
Injection Force	In-house test method
Aspiration Force	In-house test method
Label Legibility	In-house test method
Impact Force	In-house test method
Needle Protective Cap Removal Force	In-house test method
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 MixJect® Transfer Device was conducted in accordance with, 2016 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. The battery of testing included the following tests:

ISO 10993-5:2009: Cytotoxicity

ISO 10993-4: 2017: ASTM Hemolysis

ASTM F756: Hemolysis Study

ISO 10993-10:2010: Maximization and Sensitization

ISO 10993-10:2010: Intracutaneous Reactivity

ISO 10993-11:2017: Acute Systemic Toxicity

ISO 10993-11:2017: Material Mediated Pyrogenicity

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. The Sterility Validation and Bacterial Endotoxin Testing are provided within this submission.

CLINICAL DATA

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

CONCLUSION

The differences between the predicate and the subject devices do not raise any new or different questions of safety or effectiveness. The subject device, MixJect® Transfer Device is substantially equivalent to the predicate device, MixJect Dispensing Pin / with Detachable Vial Holder / with Detachable Vial Holder and Preattached Needle.