December 14, 2023

West Pharma Services IL, Ltd.
David Ceretti
Principal Regulatory Affairs Specialist
4 Hasheizaf St
Ra'anana, 4366411
Israel

Re: K232875
Trade/Device Name: Vial Adapter 20mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: September 14, 2023
Received: September 15, 2023

Dear David Ceretti:

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
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)*
K232875

Device Name
Vial Adapter 20mm

Indications for Use *(Describe)*
The Vial Adapter is indicated for the transfer 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.

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K232875- 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.
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Facility Establishment Registration Number: 3000223297

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Date Prepared: December 14, 2023

DEVICE

Trade Name:	Vial Adapter 20mm
Common/Usual Name:	I.V. Fluid Transfer Set
Regulation Name:	Intravascular Administration Set
Product Code:	LHI
Regulation Number:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

PREDICATE DEVICE

MixJect Dispensing Pin – K001293.

No reference devices were used in this submission.

DEVICE DESCRIPTION

Device Overview

The Vial Adapter (VA) 20mm is a single-use device that allows for the transfer of drugs contained in a vial.

The device is a one-piece polycarbonate molded part with a standard female Luer port for the connection of a syringe. Puncturing the elastomeric closure of a drug vial is achieved by means of an integral plastic cannulated spike located in the center of the Vial Adapter component. The VA 20mm device is supplied with or without an inline filter, based on catalog number.

The VA is sterilized utilizing gamma irradiation and is packaged in a Polyethylene Terephthalate Glycol (PETG) blister enclosure. The VA 20mm is packaged in either a Vial First (VF) or a Syringe First (SF) orientation, which function as follows:

> The VF packaging orientation allows the VA 20mm device to be attached to a vial immediately after the removal of the packaging Tyvek® lid stock, while still cradled by the blister pack. The blister package is then removed leaving the VA 20mm attached to the vial.
>
> The SF packaging orientation allows the VA 20mm device to be attached to a syringe immediately after the removal of the packaging Tyvek® lid stock, while still cradled by the blister pack. Using the syringe, the VA 20mm device is then removed from the blister packaging.

The device does not contain any medicinal substances or moving parts and is intended for use with standard drug vials having a neck diameter of 20mm.

Principle of Operation

The VA 20mm device is operated by a manual process. The subject device connects to a drug vial (supplied by the Drug Manufacturer) having a neck diameter of 20mm, along with a female Luer Lock. The VA 20mm contains an integral plastic cannulated spike located in the center of the VA, 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 syringe. Depending on the catalog number ordered, the VA 20mm cannulated spike may be provided lubricated with a sterile silicone compound.

For the Syringe First (SF) Female Luer Lock (FLL) Vial Adapter, a prefilled slip syringe is connected to the female Luer Lock port located on the top of the SF FLL VA by turning the syringe clockwise until secure. Once the vial and syringe are firmly attached to the SF FLL VA, the diluent is then injected into the vial. The drug is then aspirated back into the syringe by means of inverting SF FLL VA with the vial up and pulling the plunger downward. The vial and device are then inverted with the vial down and the syringe is then manually rotated in a counterclockwise direction, allowing the syringe to be removed from the SF FLL VA. The drug is then ready for administration per the instructions in the drug manufacturer's packaging insert.

For the Vial First (VF) Female Luer Lock (FLL) Vial Adapter, the VF FLL VA is firmly attached to the vial. A prefilled slip syringe is connected to the VF FLL VA, interfacing with the female Luer Lock port located on the top of the VF FLL VA, by turning the syringe clockwise until a secure connection is obtained. The diluent is then injected into the vial. The drug is then aspirated back into the syringe by means of inverting VF VA with the vial up (vertical) and pulling the plunger downward. The vial and subject device are then inverted with the vial down and the Syringe is then manually rotated in a counterclockwise direction, allowing the syringe to be removed from the VF FLL VA. The drug is then ready for administration per the instructions in the drug manufacturer's packaging insert.

INDICATION FOR USE

The Vial Adapter is indicated for the transfer of drugs contained in a vial.

SUBSTANTIAL EQUIVALENCE COMPARISON

The Vial Adapter 20mm is substantially equivalent in its intended use, design/construction, technology/principle of operation, materials, and performance to the predicate device MixJect Dispensing Pin, cleared under K001293.

Indications for Use Comparison Summary

The Indications for Use statement for the Vial Adapter is not identical to the predicate device. However, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

The subject device is indicated for the transfer of drugs contained in a vial.

The predicate device is indicated for the transfer and mixing of drugs contained in a vial.

The mixing claim has been removed from the subject device labeling, including the Indications for Use statement. As indicated in the device Instructions for Use, the mixing operation is defined by the Drug manufacturer. Therefore, West Pharmaceutical Services, Inc does not maintain verification or validation data within the device Design History File to substantiate the mixing claim.

The subject device, Vial Adapter, and predicate device, MixJect Dispensing Pin, have identical regulation number / code, product code, and device classification.

Both devices are intended for use by Health Care Professionals (HCP) in hospitals or healthcare facilities.

Technological Characteristics Comparison Summary

The subject device is identical to the predicate device in its operation principles, compatible vial size, body diameter, piercing spike (with a siliconization option), vial adapter fit, material, sterility method, and packaging.

Similarities can be found in the packaging design as both the subject and predicate device are packaged in vial first configuration, while the subject device also has a syringe first configuration option. Additionally, the subject device can withstand a shelf life of 5 years, while the predicate had been cleared for 3-year shelf-life.

The differences between the subject and the predicate device consist of a new tight grip and an optional inline mesh filter in the subject device, not previously available for the predicate device. Further, the Luer connector design construction in the subject device has been redesigned to be compliant with ISO 80369-7:2021 vs. the predicate device being compliant with ISO 594-1 and ISO 594-2.

A comparison of equivalence and differences between the subject device and the predicate device is provided in the table below.

Substantial Equivalence Comparison Table

Areas for Comparison	**Subject Device** Vial Adapter 20mm	**Predicate Device (K001293):** MixJect Dispensing Pin	**Comparison**
General Information			
Device Trade Name	Vial Adapter	MixJect Dispensing Pin	**Different:** A business decision was made to change the name of the MixJect Dispensing Pin to Vial Adapter 20mm for marketing purposes.
Indications for Use	Transfer of drugs contained in a vial	Transfer and mixing of drugs contained in a vial.	**Different:** Removal of "mixing" claim since drug mixing instructions are provided by the customer, not West Pharmaceutical Services (WPS). Therefore, WPS does not have Verification / Validation data on file to substantiate this claim and consequently has removed this claim. This claim removal does not raise new or additional concerns regarding device safety profile or clinical effectiveness.
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**
Prescription Use	Yes	Yes	**Identical**
Single Use	Yes	Yes	**Identical**

Areas for Comparison	**Subject Device** Vial Adapter 20mm	**Predicate Device (K001293):** MixJect Dispensing Pin	**Comparison**
Shelf life	5 years	3 years	**Different:** The subject device packaging and performance has been tested and determined to withstand a shelf life of 5 years, per ASTM F1886, in comparison to the predicate device withstanding a shelf life of 3 years. These changes do not raise new or additional concerns regarding device safety profile or clinical effectiveness.
Design			
Operation Principle	Manual	Manual	**Identical**
Design/construction	Featuring a 20mm Vial Adaptor, with and without tight grip hold ("wings") and filter intended to be attached to a standard drug vial with a neck diameter of 20mm. The device contains either a silicon or non-silicone piercing spike, and a female Luer Lock fitting compliant with ISO 80369-7:2021, for attachment to a standard accessory such as a syringe (not supplied)	Featuring a 20mm Vial Adaptor intended to be attached to a standard drug vial with a neck diameter of 20mm. The device contains a silicone and non-silicone piercing spike, 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).	**Different –**The differences noted with ISO Luer Standard compliance, and additional tight grip and filter options do not alter the device intended use, clinical effectiveness, or safety profile. These changes do not raise new or additional concerns regarding the device's safety profile or clinical effectiveness.
Female and Male Luer Lock Connector	Complaint with ISO 80369-7:2021	Complaint with ISO 594-1 and ISO 594-2	**Different –** Subject device updated for compliance with latest ISO Luer standard. No change in the intended use or device performance.
Compatible Vial Size	20mm	20mm	**Identical**

Areas for Comparison	**Subject Device** Vial Adapter 20mm	**Predicate Device (K001293):** MixJect Dispensing Pin	**Comparison**
Body Diameter	17.4mm (TG) and 23.6mm to accommodate 20mm standard vials	23.6mm to accommodate 20mm standard vials	**Identical -** standard 23.6mm for 20mm standard vials **Different** – Additional Tight Grip (TG) 17.4mm body diameter as the subject device is not offered in the predicate device. The addition does not raise new or additional concerns regarding device safety profile or clinical effectiveness.
Piercing Spike	Single lumen	Single lumen	**Identical**
Vial Adapter Fit	snap fit to vial	snap fit to vial	**Identical**
Material	Vial Adapter Body/Vial Holder: Polycarbonate Lubricant (optional): DOWSIL 360 Medical Fluid In-Line Filter (optional): Polyethylene Mesh	MixJect Body / Vial Holder: Polycarbonate Lubricant: DOWSIL 360, Medical Grade	**Identical -** The Body/Vial Holder and lubricant material is identical. **Different -** The subject device also has an optional in-line filter, not offered with the predicate device. These additions do not raise new or additional concerns regarding the device's safety profile or clinical effectiveness.
Biocompatibility	ISO 10993-1:2018 External Communicating, Limited Contact (≤ 24 hrs.)	ISO 10993-1 and USP Biological Reactivity External Communicating, Limited Contact (≤24 hrs.)	**Identical**
Non-pyrogenic	Yes	Yes	**Identical**
Sterilization			
Sterility	Terminal Sterilization	Terminal Sterilization	**Identical**

Areas for Comparison	**Subject Device** Vial Adapter 20mm	**Predicate Device (K001293):** MixJect Dispensing Pin	**Comparison**
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, or syringe 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.	**Different** – The subject device contains a Vial First (VF) packaging orientation, identical to the predicate, with an additional Syringe First (SF) orientation option as well. The addition does not raise new or additional concerns regarding device's safety profile or clinical effectiveness.

PERFORMANCE DATA

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

Performance Testing

Performance testing conducted confirms the Vial Adapter 20mm meets all applicable design and performance requirements throughout its defined shelf life, conforms to applicable external and internal standards, and demonstrates substantial equivalence to the predicate device. The table below lists all non-clinical bench performance tests completed for 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

Test	Test Method/ Standard
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 Table B.2 and B.5 (compliance to dimensions)
Residual Volume	In-house test method
Device Leakage	In-house test method
Device Leakage under normal use	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
Device Removal Force from Blister	In-house test method
Tyvek Total Peel Test	In-house test method
Functionality according to IFU	In-house test method
Filter Efficiency	In-house test method
Syringe First Orientation	In-house test method

Test	Test Method/ Standard
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
Packaging Integrity	In-house test method

Performance testing and a risk management file review indicate all product design requirements are verified and the residual risk level is acceptable. Together, the 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

In accordance with ISO 10993-1:2018, the subject device, Vial Adapter 20mm, is classified as an externally communicating device, having limited indirect contact with the patient's blood path (≤24 hours). The biocompatibility evaluation for the Vial Adapter 20mm was conducted in accordance with, the 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. The following biocompatibility tests have been successfully conducted on the Vial Adapter 20mm:

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

ISO 10993-12:2012: Solvent and Extraction Condition

Based on the results of biocompatibility testing, the device materials are considered biologically safe when the device is used as intended. The biocompatibility results demonstrate the subject device does not present new concerns regarding safety and effectiveness. Therefore, the subject device Vial Adapter 20mm, is considered substantially equivalent to the predicate device.

Sterilization

The subject device is terminally sterilized using a Gamma irradiation sterilization method, validated in accordance with standard *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 *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 results of the Sterility Validation and Bacterial Endotoxin Testing are provided within this submission.

CLINICAL DATA

Clinical trials were not performed for the Vial Adapter 20mm.

CONCLUSION

In summary, the subject device Vial Adapter 20mm is determined to be substantially equivalent in technology, principles of operation, materials, and performance to the predicate device, MixJect Dispensing Pin, cleared under K001293.