August 31, 2022

West Pharma Services IL, Ltd.
% Fred Cowdery
Director, Regulatory Affairs (Medical Devices)
West Pharmaceutical Services, Inc.
530 Hermon O. West Drive
Exton, Pennsylvania 19341

Re: K213513
Trade/Device Name: Vented Vial Adapter 20mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: July 29, 2022
Received: August 1, 2022

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,

David Wolloscheck, Ph.D.
For Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213513

Device Name
Vented Vial Adapter 20mm

Indications for Use *(Describe)*
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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K213513 - 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:

Fred Cowdery
Director Regulatory Affairs, Medical Devices Phone:
484-787-6834
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Date Prepared: 31 August 2022

Classification:

Trade Name:	Vented Vial Adapter 20mm
Common/Usual Name:	I.V. Fluid Transfer Set
Product Code:	LHI
Regulation No.:	21 CFR 880.5440
Regulation Name:	Intravascular Administration Set
Class:	II
Panel Identification:	General Hospital Panel

Predicate Device(s): Vented Vial Adapter Transfer Device – 13mm (K160503)

Device Description

Device Design and Operation

The subject Vented Vial Adapter HU is being developed as a new offering to the market. The Trade Name of the subject device is Vented Vial Adapter 20mm, while the Common/Usual Name is Vented Vial Adapter HU. By altering the Common/Usual Name from the Trade Name, the intention is to differentiate the subject device from the predicate device and any potential future submissions.

The Vented Vial Adapter HU, is a single use, sterile, non-pyrogenic medical device intended for the transfer of drugs contained in a vial. The device is intended for use in the preparation of drugs for home use, in hospitals, or outpatient nursing units as used/administered by the patient, caregiver, or Healthcare Professionals (HPCs). The subject device is by prescription use only and does not have contraindications. The device does not contain any medicinal substances and there are no additional accessories provided for use with the product. The device has a 3-year shelf life.

The Vented Vial Adapter HU allows for the connection of a standard accessory with a female Luer lock to be connected to a vial. The vial adapter body with tight grip hold ("wings") is intended to be attached to a standard drug vial with a neck diameter of 20mm. The device contains a piercing spike, cap with air filter, vent and a female Luer lock connector for attachment to a standard accessory. This dual lumen spike design facilitates rapid withdrawal of the drug/solution without pressurizing the vial by allowing inbound air aspiration through the air filter.

The materials of construction of the VVA HU body and cap are polycarbonate, with a 0.2µm hydrophobic air filter comprised of 100% expanded PTFE membrane over non-woven polyester membrane support.

Principle of Operation

The Vented Vial Adapter HU is operated by manual process. The subject device is first attached to the drug vial with a neck diameter of 20mm (supplied by the Drug Manufacturer). Puncturing of the elastomeric stopper on a drug vial is achieved by means of the integrated plastic cannulated spike located in the center of the vial adapter. This piercing spike consists of two lumens. The main lumen of the piercing spike is for transfer of fluids/solution between the vial and the syringe, the second lumen enables pressure equilibrium between the vial content and the environment by introducing air through the 0.2µm hydrophobic air filter, located in the device cap. A syringe/accessory (supplied by the Drug manufacturer) with a female Luer lock is attached to the subject Vented Vial Adapter HU.

The process of transfer is performed through the attachment of drug-containing vial and syringe with diluent to the Vented Vial Adapter HU. Transfer of diluent into the vial takes place by injecting the diluent. Upon reconstitution, the drug is then withdrawn into the syringe by turning the vial up-side down. After reconstitution and withdrawal, the syringe is removed by twisting it counterclockwise and the drug is ready for administration through attached needle/syringe. There are no accessories provided with the subject device, as the user will be supplied with the drug vial and needle-less syringe/accessory by the Drug Manufacturer.

Indications for Use:

Transfer of drugs contained in a vial.

Technological Characteristics and Substantial Equivalence:

The Vented Vial Adapter HU, is substantially equivalent in its intended use, design/construction, technology/principle of operation, materials, and performance to the predicate device Vented Vial Adapter Transfer Device – 13mm, which is cleared under K160503.

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

Substantial Equivalence Comparison

Areas for Comparison	**Subject Device:** Vented Vial Adapter HU	**Predicate Device (K160503):** Vented Vial Adapter Transfer Device – 13mm	**Comparison**
General Information			
Manufacturer	West Pharma. Services IL, Ltd.	Medimop Medical Projects, Ltd./West Pharma. Services IL., Ltd. (acquired by West Pharmaceutical Services, Inc. and name changed to West Pharma. Services IL, Ltd.)	**Identical**
Indications for Use	Transfer of drugs contained in a vial.	Transfer and mixing of drugs contained in a vial.	**Equivalent** The predicate device has reduced claims (removal of mixing). This difference is considered minor and does not raise new or additional questions concerning safety and effectiveness.
Intended Population	Intended for use by patient, care giver and Healthcare Professionals (HCPs)	Intended for use by patient, care giver and Healthcare professionals (HCPs)	**Identical**
Intended Environment	Intended for use at home, in hospitals, or outpatient nursing units	Intended for use in healthcare facilities, or in the home environment	**Identical**
Device Class & Classification Name	Class II, Set, I.V. Fluid Transfer	Class II, Set, I.V. Fluid Transfer	**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	3 years	3 years	**Identical**
Design			
Operation Principle	Manual	Manual	**Identical**

Areas for Comparison	**Subject Device:** Vented Vial Adapter HU	**Predicate Device (K160503):** Vented Vial Adapter Transfer Device – 13mm	**Comparison**
Design/construction	Featuring a 20mm Vented Vial Adaptor body with tight grip hold ("wings"), intended to be attached to a standard drug vial with a neck diameter of 20mm. The device contains a piercing spike, cap with air filter, vent and a female Luer lock (BS EN ISO 80369-7:2016) connector for attachment to a standard accessory to access drug content.	Featuring a 13mm Vented 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, cap with air filter, vent and a female Luer lock (ISO 594-1:1986, ISO 594-2:1998) connector for attachment to a standard accessory to access drug content.	**Equivalent device size and Luer lock ISO std - See Device Description Section**
Female Luer Lock	Complaint with BS EN ISO 80369-7:2016	Compliant with ISO 594-1:1986 and ISO 594-2:1998	**Equivalent - See Performance Section**
Compatible Vial Size	20mm	13mm	**Equivalent - See Device Description Section**
Body Diameter	30.1mm to accommodate 20mm standard vials	18.5mm to accommodate 13mm standard vials	**Equivalent - See Device Description Section**
Piercing Spike	Dual lumen, non-siliconized	Dual lumen, non-siliconized	**Identical**
0.2µm Hydrophobic Air Filter Purpose	In concert with lumen, allows for pressure equilibrium between the environment and vial contents through introduction of air through vent in vial adapter cap	In concert with lumen, allows for pressure equilibrium between the environment and vial contents through introduction of air through vent in vial adapter cap	**Identical**
Vial Adapter Fit	Vial first, snap fit to vial	Vial first, snap fit to vial	**Identical**
Material	Vented Vial Adaptor Body (including spike): Polycarbonate Cap for Vented Vial Adaptor: Polycarbonate 0.2µm hydrophobic air filter, 100% expanded PTFE membrane over non-woven polyester membrane support	Vented Vial Adaptor Body (including spike): Polycarbonate Cap for Vented Vial Adaptor: Polycarbonate 0.2µm hydrophobic air filter, 100% expanded PTFE membrane over non-woven polyester membrane support	**Identical**
Biocompatible	Yes, Prolonged Use (24hrs – 30 days)	Yes, Limited Contact (<24hrs)	**Equivalent - See Biocompatibility Section**

Areas for Comparison	**Subject Device:** Vented Vial Adapter HU	**Predicate Device (K160503):** Vented Vial Adapter Transfer Device – 13mm	**Comparison**
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 Dimensions: Designed to accommodate subject device.	Sterile Barrier package materials: PETG blister with Tyvek® seal Sterile Barrier package orientation: Devices are supplied in an individual blister, vial first orientation Dimensions: Designed to accommodate predicate device	**Identical Sterile Barrier Package Materials** **Identical Sterile Barrier Package Orientation** **Equivalent Dimensions– See Device Description Section.**

Performance Data

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

Performance Testing

Performance testing was conducted to ensure that the Vented Vial Adapter HU 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. Table 5-1 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
Detachment of Cap	BS EN ISO 80369-7:2016 Section 6.4
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 80369-7:2016	ISO 80369-7:2016
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20:2015, Annex B & Annex C for the leakage reference connector (fluid leakage)
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20:2015, Annex D & Annex C for the leakage reference connector (air leakage)
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20: 2015, Annex E & Annex C for the stress cracking reference connector
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20: 2015, Annex F & Annex C for the axial load reference connector
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20: 2015, Annex G & Annex C for the resistance separation from unscrewing reference connector
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-20: 2015, Annex G & Annex C for the overriding reference connector
Luer Stability and compliance to BS EN ISO 80369-7	BS EN ISO 80369-7 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
Filter Clogging	In-house test method
Device Skirt ("wings") Position on standard 20mm Vial	ISO 8362-6:2010
Flow Rate	In-house test method
Device Removal Force from Blister	In-house test method
Tyvek Total Peel Test Force	In-house test method
Air Filter Bursting Pressure	In-house test method
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

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.

Biocompatibility Testing

In accordance with ISO 10993-1, the subject Vented Vial Adapter HU 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 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."* The following biocompatibility tests have been successfully conducted on the Vented Vial Adapter HU:

Cytotoxicity (Tested to ISO 10993-5:2009)

Sensitization (Tested to ISO 10993-10:2010)

Intracutaneous Reactivity (Tested to ISO 10993-10:2010)

Acute Systemic Toxicity (Tested to ISO 10993-11:2017)

Material Mediated Pyrogenicity (Tested to ISO 10993-11:2017)

Systemic (Subacute) Toxicity (Tested to ISO 10993-11: 2017)

ASTM Hemolysis (Tested to ISO 10993-4: 2017)

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 efficacy; therefore, the subject Vented Vial Adapter HU is considered substantially equivalent to the predicate device.

Sterilization

The sterility of the subject device is assured 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, as well as AAMI TIR 33 Sterilization of health care products – Radiation* – Substantiation of a selected sterilization dose – Method VD_{max}. 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

No clinical trial was performed for Vented Vial Adapter HU.

Conclusion

In summary, the differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Vented Vial Adapter 20mm is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate device, Vented Vial Adapter Transfer Device – 13mm (K160503).