DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 8, 2017

Medimop Medical Project Ltd.
Ms. Ilanit Goldgraber
Director, Regulatory Affairs
17 Hatidhar Street
Ra'anana, 43665
ISRAEL

Re: K170095
Trade/Device Name: Vial2Bag™ Direct Connect
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: January 9, 2017
Received: January 11, 2017

Dear Ms. Ilanit Goldgraber:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170095

Device Name
Vial2Bag Direct Connect

Indications for Use *(Describe)*
The Vial2Bag™ Direct Connect is indicated to serve as a connecting part between the IV bag and an external IV line. The integrated vial adapter makes it possible to reconstitute and admix drugs from a vial into the infusion solution.

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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510(K) SUMMARY (K170095)

Company Name:

Medimop Medical Projects Ltd
17 Hatidhar St
Ra'anana 4366519
Israel
Phone: 972-9-7757122
Fax: 972-9-7485916

Contact Person:

Ilanit Goldgraber
Director, Regulatory Affairs
Phone: 972-9-7778666
Fax: 972-9-7485916
E-mail: ilanit.goldgraber@westpharma.com

US Agent:

Kevin Lentz
Sr. Director, Regulatory Affairs
West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, PA 19341
Phone: (610) 594-4353
Email: kevin.lentz@westpharma.com

Preparation date: 3/7/2017

Classification:

Regulation Name:	Intravascular Administration Set
Trade Name:	Vial2Bag Direct Connect
Common/Usual Name:	Vial2Bag DC
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

Predicate Devices: Vial2Bag Direct Connect, cleared by 510(k) K140730

Device Description

The proposed device, Vial2Bag Direct Connect, is intended for use in healthcare facilities or in home environment by the patient or care-giver to aid and support prescribed treatment and therapy.

The proposed device, Vial2Bag Direct Connect is available with 13mm Vial Adapter or 20mm Vial Adapter. The device consists of the Vial2Bag piercing spike and cover, the twist-off connector and an integrated Vial Adapter (13mm or 20mm) for access to the drug/solution vial.

Up to 3 Vial2Bag Direct Connect can be consecutively connected by inserting the spike of one device into the twist off connector of the previous device.

The device does not contain any medicinal substances, and can be used with standard drug vials.

Indications for use
The Vial2Bag™ Direct Connect is indicated to serve as a connecting part between the IV bag and an external IV line. The integrated vial adapter makes it possible to reconstitute and admix drugs from a vial into the infusion solution.

Technological Characteristics and Substantial Equivalence Discussion:
The proposed device, Vial2Bag Direct Connect, has the same indications for use and principle of operation as the predicate device, Vial2Bag Direct Connect, from Medimop Medical Projects, Ltd, cleared by 510(k) number K140730.

The following modifications have been made to the Vial2Bag Direct Connect originally cleared by 510(k) K140730:

- Proposed device labeling (IFU) includes optional instructions for the connection of up to 3 Vial2Bag Direct Connect for consecutive connection by inserting the spike of one device into the twist off connector of the previous device.
- Vial2Bag Direct Connect 20mm S (Short) Spike option reduces the vial piercing spike length compared to the predicate device
- Vial2Bag Direct Connect 20mm C-Spike option contains larger diameter spike compared to the predicate device
- Packaging changed from Ethyl Vinyl Acetate (EVA) / Tyvek pouch to a PETG blister with Tyvek seal cover stock.
-

The predicate and proposed devices are designed and manufactured by the same organization and share the same materials and function.

The predicate and proposed devices share the same principle of operation and fundamental technology when utilizing the Vial2Bag Direct Connect.

Areas for Comparison	**Claimed Substantially Equivalent Product** **Vial2Bag Direct Connect** **K140730**	**Proposed Device** **Vial2Bag Direct Connect**	**Comparison**
Indication for Use	The Vial2Bag™ Direct Connect is indicated to serve as a connecting part between the IV bag and an external IV line. The integrated vial adapter Is used to reconstitute and admix drugs from a vial into the infusion solution.	The Vial2Bag™ Direct Connect is indicated to serve as a connecting part between the IV bag and an external IV line. The integrated vial adapter is used to reconstitute and admix drugs from a vial into the infusion solution.	Identical

Areas for Comparison	Claimed Substantially Equivalent Product Vial2Bag Direct Connect K140730	Proposed Device Vial2Bag Direct Connect	Comparison
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Identical
Single use	Yes	Yes	Identical
Body Material	Polycarbonate	Polycarbonate	Identical
Expiration Date	5 years	3 years	Modified
Vial Adapter Diameter	30.4mm to fit 20mm Vials 18.5mm to fit 13mm Vials	30.4mm to fit 20mm Vials 18.5mm to fit 13mm Vials	Identical
Labeling	Predicate device labeling (IFU) includes connection instructions to IV bag	Proposed device labeling (IFU) includes optional instructions for the connection of up to 3 Vial2Bag Direct Connect for consecutive connection by inserting the spike of one device into the twist off connector of the previous device.	Modified
Piercing Spike	Plastic - Single Lumen	Vial2Bag Direct Connect 20mm S (Short) Spike reduces the vial piercing spike length compared to the predicate device Vial2Bag Direct Connect 20mm C-Spike contains larger diameter spike compared to the predicate device	Modified
"Tight Grip" feature	Included	Included	Identical
Packaging Material	Tyvek / Ethyl Vinyl Acetate (EVA)	PETG blister and Tyvek seal	Modified

Performance Testing:

The modifications to the proposed device were evaluated within the Medimop design control system. A risk assessment was performed to ensure that the proposed device modifications did not introduce any new potential risks. The following tests were performed on the proposed device, Vial2Bag Direct Connect, as a result of the risk assessment to ensure the all potential risks associated with the device modifications were mitigated to acceptable levels.

- Product Functionality According to IFU
- Total Penetration Force
- Cap Detachment Force
- Vial Adapter Detachment Force from Drug Vial
- Breaking Torque Test
- Spike Tip Ductility Test
- Air Leakage Test
- Packaging

Performance Testing Summary	
Test Name	**Testing Standard**
Product Functionality According to IFU	Tested to internal performance standards
Total Penetration Force	Tested to internal performance standards
Detachment Force	Tested to internal performance standards
Vial Adapter Detachment Force from Drug Vial	Tested to internal performance standards
Breaking Torque Test	Tested to internal performance standards
Spike Tip Ductility Test	Tested to internal performance standards
Air Leakage Test	Tested to internal performance standards
Packaging	Tested per ISO 11607-1

All testing met the required acceptance criteria.

Sterilization

- The Vial2Bag Direct Connect is sterilized by Ethylene Oxide in a cycle validated according to standard ISO11135-1:2007 using the "overkill method". The sterilization subcontractor is Mediplast Israel Ltd.

- The sterilization process is validated to a minimum SAL 10^{-6}. Residuals of ETO and ECH were tested after two sterilization cycle and met the requirements os ISO 10993-7:2008 for prolonged exposure.

Biocompatibility

- Representative samples from every lot of product are tested for bacterial endotoxin by a validated Limulus Amoebocyte Lysate (LAL) method.
  - The acceptable Endotoxin level is 0.5 EU/ml (Endotoxin Units) or 20 EU/device.
  - The sensitivity of the LAL assay is 0.005 EU/ml.
- A biocompatibility assessment was conducted according to ISO 10993-1 and the FDA Blue Book Memorandum # G95-1 for this material following Double EtO. The Vial2Bag™ DC has been classified as follows:
  - Category: Externally Communicating
  - Contact Duration: Prolonged
  - Device Body Contact: Blood Path Indirect
- Based upon this assessment, the following biocompatibility testing has been successfully completed.
  - Cytotoxicity (Tested to ISO 10993-5)
  - Sensitization (Tested to ISO 10993-10
  - ASTM Hemolysis (Tested to ASTM F756 and ISO 10993-4)
  - Intracutaneous Reactivity (Tested to ISO 10993-10)
  - Systemic Toxicity (Acute Systemic Injection) (Tested to ISO 10993-11)
  - USP Rabbit Pyrogen (Material Mediated Pyrogenicity) (Tested to USP 151)

Conclusion

The evaluation of the proposed device, Vial2Bag Direct Connect, does not raise any additional concerns regarding safety and effectiveness and is considered to be substantially equivalent to the predicate device, Vial2Bag Direct Connect, 510(k) K140730.