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

May 4, 2016

Medimop Medical Projects Ltd.
Ilanit Goldgraber
Director of Regulatory Affairs
17 Hatidhar Street
Ra'anana, 4366519
ISRAEL

Re: K160503
Trade/Device Name: Vented Vial Adapter Transfer Device - 13mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: April 1, 2016
Received: April 4, 2016

Dear 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 yours,

for Erin I. Keith, M.S.
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)*
K160503

Device Name

Vented Vial Adapter Transfer Device – 13mm

Indications for Use *(Describe)*

The Vented Vial Adapter Transfer Device is intended for the transfer and mixing 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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510(K) SUMMARY

Device: Vented Vial Adapter Transfer Device - 13mm

Company Name:

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Preparation date: 5/4/2016

Classification:

Classification Name:	Intravascular Administration Set
Trade Name:	Vented Vial Adapter Transfer Device - 13mm
Common/Usual Name:	Vented Vial Adapter 13mm
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

Predicate Devices: Vented Vial Adapter Transfer Device, cleared by 510(K) K062482

Device Description:

The proposed device, Vented Vial Adapter Transfer Device - 13mm, 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 consists of two integrated parts, the first part is the 13mm vial adapter body intended to be attached to a standard 13 mm drug vial. The other end is intended to be connected to a Female Luer connection. The vial adapter body contains the dual lumen piercing spike and the second part of the device is an assembled 0.2µm hydrophobic air path filter (100% expanded PTFE membrane over Non-woven polyester membrane support). This enables keeping an equilibrium pressure between the drug vial and the ambient pressure, filtering the inserted/ released air through 0.2µm air filter. The proposed device does not contain any medicinal substances.

Indications for use:

The Vented Vial Adapter Transfer Device is intended for the transfer and mixing of drugs contained in a vial.

Substantial Equivalence

The proposed device, Vented Vial Adapter Transfer Device - 13mm, has the same indications for use and principle of operation as the predicate device, Vented Vial Adapter Transfer Device, from Medimop Medical Projects, Ltd, cleared by 510(k) number K062482.

The following modifications have been made to the Vented Vial Adapter Transfer Device originally cleared by 510(K) K062482:

- Dimension of body connection modified to fit a 13mm vial
- Air Filter Reversal in order to avoid clogging of the filter if the diluent is injected in upright position and, by that, to improve the usability of the device. The hydrophobic side of the filter is now facing the vent path.
- The vial adapter body was redesigned to include “tight grip” feature to improve adherence of the vial adapter to the 13mm vial. Subsequently the geometry of the individual blister package was modified to adapt the “tight grip” modification (larger internal diameter)
- The cap is attached to the body by ultrasonic welding instead of a snap fit

Technological Characteristics and Substantial Equivalence:

The Medimop Vented Vial Adapter Transfer Device – K062482 has been cleared for the transfer and mixing of drugs contained in vials and is being selected as the predicate device for this proposed device. The predicate and proposed devices are designed and manufactured by the same organization and share the same materials and function. The proposed device expands the dimensional and functional attributes of the predicate 20mm vial adapter for use with smaller 13mm vials.

The predicate and proposed devices share the same principle of operation and fundamental technology when utilizing the Vented Vial Adapter device. The Vented Vial Adapter allows the connection of any standard accessory with a Luer connection to be connected to a vial. Once mixing of the diluent and the drug is complete, the drug solution can be transferred using the vial adapter. The determination that the drug solution is ready for use is based on drug manufacturer recommendations. The vial adapter is a single use device and should be disposed of after use.

Areas for comparison	**Claimed Substantially Equivalent Product** **Vented Vial Adapter** **K062482**	**Proposed Device** **Vented Vial Adapter – 13mm** **K160503**	**Comparison**
Indication for Use	Intended for the transfer and mixing of drugs contained in vials	Intended for the transfer and mixing of drugs contained in vials	Identical
Sterilization Method	Gamma	Gamma	Identical
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Identical
Single use	Yes	Yes	Identical
Material	Polycarbonate	Polycarbonate	Identical
Expiration Date	5 years	3 years	Modified
Body Diameter	30.4mm to fit 20mm Vials 	18.5mm to fit 13mm Vials 	Modified

Areas for comparison	Claimed Substantially Equivalent Product Vented Vial Adapter K062482	Proposed Device Vented Vial Adapter – 13mm K160503	Comparison
Air Filtration	0.2 micron hydrophobic Filter Oval centered hole	0.2 micron hydrophobic Filter Round centered hole Reversed direction of flow	Modified
Cap Assembly	Assembly Attached Mechanically	Assembly Attached Ultrasonically	Modified
Vial Adapter Fit (Vial Side)	Snap Fit to Vial	Snap Fit to Vial Reduced Diameter to improve grip of 13mm Vials (i.e. "Tight Grip" Feature)	Modified
Piercing Spike	Plastic - Dual Lumen	Plastic - Dual Lumen	Identical

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 (Product functionality according to IFU, Total penetration force, detachment force from drug vial, filter bursting pressure, wet filter test, cap detachment from body, internal stress level, system leakage and biocompatibility) were performed on the proposed device, Vented Vial Adapter Transfer Device 13 mm, as a result of the risk assessment to ensure the all potential risks associated with the device modifications were mitigated to acceptable levels.

- Dimension change to 13mm
- Addition of 'Tight Grip' feature
- Reverse air filter direction
- Use ultrasonic welding for cap attachment to body

Performance Testing Summary	
Test Name	**Testing Standard**
Product Functionality Performance test according to IFU	Tested to internal performance standards
Filter Bursting Pressure	Tested to internal performance standards
Flow Rate Testing	Tested to internal performance standards
Cap/valve-housing detachment from body Test	Tested to internal performance standards
Internal stress level for assembled product	Tested to internal performance standards
Biocompatibility	Tested per ISO 10993-1

All testing met the required acceptance criteria.

Conclusion

The evaluation of the proposed device, Vented Vial Adapter Transfer Device - 13mm, does not raise any additional concerns regarding safety and effectiveness and is considered to be substantially equivalent to the predicate device, Vented Vial Adapter Transfer Device, 510(k) K062482.