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

October 12, 2017

Medimop Medical Project Ltd.
Mr. Jeffrey Ravel
Director, Regulatory Affairs
17 Hatidhar Street
Ra'anana, 43665
ISRAEL

Re: K171796
Trade/Device Name: Vial Adapter 15mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: September 19, 2017
Received: September 20, 2017

Dear Mr. Jeffrey Ravel:

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" (21CFR 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

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*

K171796

Device Name
Vial Adapter 15mm

Indications for Use *(Describe)*
The Vial Adapter 15mm is indicated for the transfer and mixing of drugs contained in vials

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 K171796

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Preparation date: 15 June 2017

Classification:

Regulation Name:	Intravascular Administration Set
Trade Name:	Vial Adapter 15mm
Common/Usual Name:	Set, I.V. Fluid Transfer
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

Predicate Devices: Mixject Dispensing Pin – K963583

Device Description

The vial adapter is a one piece molded polycarbonate device that is used to aide in the reconstitution and transfer of drugs contained in vials. The sterile device pierces the elastomeric septum of a drug vial with its integrated spike. The device is then pushed fully onto the drug vial and seats securely around the ferrule of the drug vial utilizing the "legs" of the vial adapter. The opposing side of the vial adapter contains a Luer fitting for the connection of a standard Luer Lock syringe for the reconstitution and removal of the contents of the drug vial. After drug removal, the syringe is removed and the vial adapter is properly discarded with the drug vial.

The proposed device, Vial Adapter 15mm, 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, Vial Adapter 15mm is a 15mm version of the currently available 13mm Vial Adapter or 20mm Vial Adapter. The device consists of a piercing spike and integrated Vial Adapter (15mm) for access to the drug/solution vial.

The device does not contain any medicinal substances, and can be used with standard drug vials. It is intended for use in healthcare facilities or in home environment by a care-giver to aid and support prescribed treatment and therapy.

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

Indications for use

The Vial Adapter 15mm is indicated for the transfer and mixing of drugs contained in vials.

There are no differences between the predicate and proposed devices indication for use.

Technological Characteristics and Substantial Equivalence Discussion:

The proposed device, Vial Adapter 15mm, has the same indications for use and principle of operation as the predicate device, MixJect Dispensing Pin, from Medimop Medical Projects, Ltd, cleared by 510(k) number K963583.

The following modifications have been made to the Vial Adapter originally cleared by 510(k) K963583:

- Proposed device size offering includes addition of a 15mm Vial Adapter
- The vial adapter body was redesigned to include "tight grip" feature to improve adherence of the vial adapter to the drug vial. Subsequently the geometry of the individual blister package was modified to adapt the "tight grip" modification (larger internal diameter)
- The packaging dimension has been changed from the current marketed 13 and 20mm Vial Adapters to accommodate a 15mm Vial Adapter.

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 Vial Adapter 15mm.

Areas for Comparison	Claimed Substantially Equivalent Product 20mm / 13mm Vial Adapter K963583	Proposed Device Vial Adapter 15mm Subject 510(k)	Comparison
Indication for Use	Transfer and mixing of drugs contained in vials	Transfer and mixing of drugs contained in vials	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	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	5 years	Identical
Vial Adapter Size	20mm / 13mm	15mm	Modified
Labeling	Predicate device labeling (IFU) includes transfer and mixing instructions	Proposed device labeling (IFU) includes transfer and mixing instructions	Identical
Piercing Spike	Plastic - Single Lumen	Plastic - Single Lumen	Identical
Vial Adapter Fit (Vial Side)	Snap Fit to Vial	Snap Fit to Vial "Tight Grip" Feature	Modified
Packaging Size	Dimensioned for 13/20mm VA	Dimensioned for 15mm VA	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, Vial Adapter 15mm, as a result of the risk assessment to ensure the all potential risks associated with the device modifications were mitigated to acceptable levels.

- Total Penetration Force

- Removal From Blister
- Vial Adapter Detachment Force from Drug Vial
- Spike Tip Ductility Test
- Fluid Leakage Test
- Packaging

Performance Testing Summary	
Test Name	**Testing Standard**
Total Penetration Force	Tested to internal performance standards
Removal From Blister	Tested to internal performance standards
Vial Adapter Detachment Force from Drug Vial	Tested to internal performance standards
Spike Tip Ductility Test	Tested to internal performance standards
Fluid Leakage Test	Tested to internal performance standards
Packaging • Visual • Peel Test • Seal Test • Methylene Blue • Bubble Leak	Tested per ISO 11607-1
Biocompatibility	Tested per • ISO 10993-1 • ISO 10993-4 • ISO 10993-5 • ISO 10993-10 • ISO 10993-11 • USP <151>

All testing met the required acceptance criteria.

Sterilization

- The Vial Adapter 15mm is sterilized by Gamma irradiation in a method validated according to standard ISO 11137-1, ISO 11137-2 and AAMI TIR 33. The sterilization subcontractor is Sor-Van Radiation Ltd.
- The sterilization process is validated to a minimum SAL 10^{-6}.

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 Gamma Irradiation. The Vial Adapter 15mm has been classified as follows:
    - Category: Externally Communicating
    - Contact Duration: Limited (Less than 24 hours)
    - 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, Vial Adapter 15mm, has demonstrated through functional performance testing to be substantially equivalent to the predicate device, Mixject Dispensing Pin – K963583.