5 510(K) SUMMARY

Device: **Vial2Bag™ Direct Connect**

Company Name:

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Preparation date: March 17, 2014

Classification:

Classification name: IV Administration Set

Trade name: Vial2Bag™ Direct Connect

Common/usual name: Vial2Bag™ Direct Connect

Product Code: LHI

Regulation No.: 880.5440

Class: II

Panel identification: General Hospital Panel

Predicate Devices:

Vial2Bag™ from Medimop Medical Projects, Ltd, cleared by 510(k) number **K072759**

Mixject Dispensing Pin (Vial Adapter) from Medimop Medical Projects, Ltd cleared by 510(k) number **K001293**

Device Description:

The proposed device, Vial2Bag™ Direct Connect, consists of the Vial2Bag™ piercing spike and cover, the twist-off connector and an integrated Vial Adapter for access to the drug/solution vial. It 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.

Indications for use:

The proposed device, 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.

Substantial equivalence

The proposed device, Vial2Bag™ Direct Connect has the same intended use, materials of construction and principle of operation as the predicate devices, Vial2Bag™ device (K072759) and the Mixject Dispensing Pin (Vial Adapter) (K001293) manufactured by Medimop Medical Projects Ltd. Therefore, the Vial2Bag™ Direct Connect is substantially equivalent to the predicate devices.

Performance Testing

Bench testing was performed to verify design requirements and to mitigate any potential risks. All bench testing was performed following double EtO sterilization to ensure that the sterilization process does not have a detrimental effect on the proposed device, Vial2Bag™ Direct Connect performance. The following tests were completed and all of them passed the established acceptance criteria.

- Air leakage test
- Vial adapter detachment force from Vial2Bag™ body
- Vial adapter breaking torque
- Vial adapter total vial penetration force
- Vial adapter detachment force from vial
- Vial adapter spike damage

Biocompatibility Tests

The proposed device, Vial2Bag™ Direct Connect, is classified as an external communicating device with prolonged indirect blood contact (24 hours to 30 days). The following tests were performed. All the tests passed the established acceptance criteria.

- Cytotoxicity (MEM Elution –ISO)
- Sensitization (ISO Guinea Pig Maximization Sensitization Test)
- Irritation / Intracutaneous (ISO Intracutaneous Study in Rabbits)
- Hemocompatibility (In Vitro Hemolysis Study – Extraction Method)
- Acute Systemic Toxicity (ISO Systemic Toxicity Study in Mice)
- Material Mediated Pyrogenicity (USP Rabbit Pyrogen Extraction Method)
- Bacterial Pyrogenicity (LAL Test Method)

Conclusion

Evaluation of the proposed device, Vial2Bag™ Direct Connect does not raise any additional concerns regarding safety and effectiveness. Therefore, it is considered substantially equivalent to the predicate devices, the Vial2Bag™ device (K072759) and the Mixject Dispensing Pin (Vial Adapter) (K001293).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Medimop Medical Projects Limited
Mr. Ilanit Goldgraber
17 Hatidhar Street
Ra'anana 4366519
ISRAEL

Re: K140730
Trade/Device Name: Vial2Bag Direct™ Connect
Regulation Number: 21 CFR 880.5440
Regulation Name: Vial2Bag Direct™ Connect
Regulatory Class: II
Product Code: LHI
Dated: March 17, 2014
Received: March 24, 2014

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

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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)*
K140730

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.06.12 14:06:42 -04'00'

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