November 19, 2019

Avenir Performance Europeenne Medical (APEM)
℅ Om Singh
Senior Scientific Consultant
Technology Sciences Group, Inc.
1150 18th Street, NW, Suite 1000
Washington, District of Columbia 20036

Re: K190816
Trade/Device Name: Vial Adapter Ø20 mm, Vial Adapter Ø13 mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: October 22, 2019
Received: October 22, 2019

Dear Om Singh:

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,

for Geeta Pamidimukkala
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190816

Device Name
Vials Adapters Ø20mm
Vials Adapters Ø13mm

Indications for Use *(Describe)*

Vials Adapters Ø20 mm and Ø13mm are 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 – K190816

1. Submitter:

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Preparing Date: Oct. 22, 2019

US Agent:

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2. Device name and classification:

Regulation Name: Intravascular Administration Set

Trade Name: Vial adapter

Common/ Usual Name: Vial Adapter Ø20mm

Vial Adapter Ø13mm

Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel identification:	General Hospital Panel

3. Predicate Device: Vial Adapter 15mm - K171796 (Medimop Medical Project Ltd.)

4. Device Description:

The vial Adapters (VA) Ø20mm and Ø13mm are sterile polycarbonated devices which allows easy transfer of fluids into and out of drug vials. It incorporates a siliconized hollow spike for puncturing the stopper in the neck of a vial and a luer fitting that allows connection of a syringe on opposite side. After puncturing the hollow spike seats securely around the ferrule of drug vial utilizing the "legs" of the vial adapter. The opposite 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. The proposed VA is available in two Ø20 mm and Ø13mm diameter to accommodate respective size of drug vials and is available in 3 configurations, no filter, in-line 5-micron or 15-micron disc filter sub- assembly for particulate filtration.

5. Indication for use:

Vial Adapter Ø20mm and Ø13mm are indicated for the transfer and mixing of drugs contained in vials.

6. Intended use:

Vial Adapter are intended for use in healthcare facilities or in-home environment by the patient or care-giver to aid and support prescribed treatment and therapy.

7. Technological Characteristics and Substantial Equivalence:

The proposed device, Vial Adapter Ø20mm and Ø13mm has the similar indications for use and

the same principle of operation as the predicate device, Vial Adapter (K171796). However, following differences were noted in device design:

The proposed device is offered in different size, i.e., Ø20mm and Ø13mm, however this difference is for a different diameter vial, but the intended use is the same. The size difference of proposed device led to the difference in packaging size from the predicate. The sterilization process is validated to a minimum SAL 10^{-6}. The proposed device can be equipped with an in-line 5-micron or 15-micron disc filter sub- assembly for particulate filtration. The performance testing of the filters met required acceptable criteria. These differences in device design do not raise different questions of safety and effectiveness.

The predicate and proposed devices share the same principle of operation and fundamental technology when utilizing the proposed device. The following table compares Vial Adapter Ø20 mm and Ø13 mm to the Predicate Device Vial Adapter 15 mm with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison of proposed Vial Adaptor Ø20 mm and Ø13mm to the predicate device Vial Adapter 15 mm (K171796)

Parameter	**Proposed Device Vial Adapter Ø20 mm and Ø13mm**	**Predicate (K171796) Vial Adapter 15mm** (Medimop Medical Project Ltd.)	**Comparison**
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same
Regulation Name	Intravascular administration set	Intravascular administration set	Same
Regulatory Class	II	II	Same
Product Code	LHI	LHI	Same

Indications for Use	Vials Adapter Ø20 mm & Ø13mm are indicated for the transfer and mixing of drugs contained in vials.	The Vial Adapter 15mm is indicated for the transfer and mixing of drugs contained in vials.	Size difference
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same
Single use	Yes	Yes	Same
Body Material	Polycarbonate	Polycarbonate	Same
Expiration Date	5 years	5 years	Same
Vial Adapter Size	20 mm and 13 mm	15 mm	Different
Labeling	Proposed device labeling (IFU) includes transfer and mixing instructions	Predicate device labeling (IFU) includes transfer and mixing instructions	Same
Piercing Spike	Plastic - Single Lumen	Plastic - Single Lumen	Same
Vial Adapter Fit (Vial Side)	Snap Fit to Vial "Tight Grip" on RayDyLyo® plastic cap	Snap Fit to Vial "Tight Grip" Feature that fits on any stopper on the vial	Same
Packaging Size	Dimensioned for VA 20 mm and 13 mm	Dimensioned for 15 mm VA	Different
Filtration	No filter, 5-micron or 15- micron disc filter configuration	No filter	Different

8. Substantial Equivalence:

The proposed device, Vial Adapter Ø20mm and Ø13mm, has the same intended use and substantially similar indications for use, technological characteristics and principles of operation as the identified predicate device. Differences in the size of vial adapters Ø20mm and Ø13mm are for different diameter vials, but intended use is the same. Based on the size differences, the packaging size differ from the predicate device. The sterilization process is validated to a minimum SAL 10^{-6}. The configurations of in-line 5-micron or 15-micron disc filter sub- assembly for particulate filtration is different than that of the predicate. However, the performance testing of the filters met required acceptable criteria. There are no significant differences between the vial adapters Ø20mm and Ø13mm and the predicate device that would adversely affect the use of the product. Any differences in technological characteristics do no raise new questions of safety or effectiveness. Further, testing demonstrates substantially equivalent performance between the device and the predicates. Accordingly, the Vial Adapter Ø20mm and Ø13mm are substantially equivalent to the predicate device in design, function, material, and intended use.

9. Summary of Non-Clinical Testing:

The vial adapter was evaluated, and risk assessment was performed to ensure that the device modifications did not introduce any new potential risks.

The following tests were performed as a result of the risk assessment to ensure that all potential risks associated with the device design are mitigated to acceptable levels.

Non-Clinical/ Performance testing Summary

Performance Testing Summary

A: Packaging		**Testing standard**
A1	Seal integrity test by dye penetration	ISO 11607-1
A2	Sealing strength (resistance)	ISO 11607-1

A3	Peeling open characteristics test	ISO 11607-1
A4	VA Extraction force from blister	Internal performance standards
A6	Blister Dimensional Control	According Drawings
B: Mechanical tests and leaks		**Testing standard**
B1	VA Snapping force	Internal performance standards
B2	VA Unsnapping force	Internal performance standards
B3	Leak Spike/Vial	ISO 8871- 5:2016(F)
B6	Spike ductility	Internal performance standards
D: Fluid flow		**Testing standard**
D1	Flow injection from syringe to Vial	Internal performance standards
D2	Flow aspiration from Vial to syringe	Internal performance standards
D3	Dead volume	Internal performance standards
E: Filter		**Testing standard**
E1	Filter integrity	Internal performance standards
E2	Filter holding force / VA	Internal performance standards
E3	Leak external filter / internal VA	Internal performance standards
E4	Particle Filtration Efficiency (Particulate)	Internal specification
F : Luer Lock		**Testing standard**

F1	Gauging	ISO 80369-7
F2	Liquid leak Checking of the liquid-tightness of the cone Luer	ISO 80369-7
F3	Air leak Checking of the air- tightness of the cone Luer	ISO 80369-7
F4	Separation force	ISO 80369-7
F5	Unscrewing torque force	ISO 80369-7
F6	Friendly assembly	ISO 80369-7
F7	Thread resistance	ISO 80369-7
F8	Cracks and change color	ISO 80369-7

Particulate Testing per USP <788>; All testing met the required acceptance criteria.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

11. Sterilization

Vial Adapter Ø20mm and Ø13mm are sterilized by Gamma irradiation in accordance to standard ISO 11137-1, ISO 11137-2 and AAMI TIR 33. The sterilization subcontractor is STERIS AST (Applied Sterilization Technologies). The sterilization process is validated to a minimum SAL 10^{-6}.

12. Biocompatibility

LAL testing

Bacterial endotoxin by a validated Limulus Amoebocyte Lysate (LAL) method.

The biocompatibility assessments were conducted according to ISO 10993-1. The following biocompatibility testing has been successfully completed.

a. Cytotoxicity (Tested to ISO 10993-5)
b. Sensitization (Tested to ISO 10993-10)
c. ASTM Hemolysis (Tested to ASTM F756 and ISO 10993-4)
d. Intracutaneous Reactivity (Tested to ISO 10993-10)
e. Systemic Toxicity (Acute Systemic Injection) (Tested to ISO 10993-11)
f. Rabbit Pyrogen Test (Material Mediated Pyrogenicity) USP <151>

13. Conclusion

The evaluation of the Vial Adapter Ø20mm and Ø13mm through performance testing demonstrates that the device is substantially equivalent to the predicate device.