October 28, 2022

Jiangsu Caina Medical Co., Ltd.
Jianwei Pan
Regulatory Affairs
No.23, Huanxi Road, Zhutang Town
Jiangyin, Jiangsu 214415
China

Re: K221406
Trade/Device Name: Vented Vial Transfer Pin
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: September 27, 2022
Received: September 30, 2022

Dear Jianwei Pan:

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 and Part 809); 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,

David Wolloscheck, Ph.D.
For Payal Patel
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)*
K221406

Device Name
Vented Vial Transfer Pin

Indications for Use *(Describe)*
The Vented Vial Transfer Pin 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K221406 - 510(k) Summary

1. Date of Preparation: Oct. 28, 2022

2. Sponsor Identification

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4. Identification of Proposed Device

Trade Name: Vented Vial Transfer Pin

Regulatory Information
Classification Name: Intravascular administration set

Common Name: I.V. Fluid Transfer Set

Classification: II
Product Code: LHI
Regulation Number: 21 CFR 880.5440
Review Panel: General Hospital

Indications for Use Statement:
The Vented Vial Transfer Pin is intended for the transfer and mixing of drugs contained in a vial.

5. Device Description

The proposed device consists of five components: (1) Protective cap, (2) Piercing spike, (3) Filter medium, (4) Filter shell, (5) Luer connector cap. The piercing spike contains the dual lumen channel for liquid and air. A 0.2μm hydrophobic air filter medium is assembled to the end of air channel. This enables keeping an equilibrium pressure between the drug vial and the ambient pressure, filtering the inserted/released air through filter medium. There is a female Luer lock connector in the end of liquid channel, it can be attached a device with a male Luer connector (e.g., standard syringe). The proposed device is available 2 specifications according to design, with security clip and without security clip. The Vented Vial Transfer Pin with Security Clip designed which can be fixed to a 13mm drug vial to prevent accidental separation.

The proposed device is a sterile, single use device. It is sterilized by Ethylene Oxide Gas (EtO) to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of five years.

No DEHP, BPA and Natural Rubber Latex are added in the proposed device.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K160503
Product Name: Vented Vial Adapter Transfer Device - 13mm

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 AMD.1:2019 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials

- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications -Part 7:Connectors for intravascular or hypodermic applications
- ISO 8536-4:2019 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed

7. Clinical Test Conclusion

Not applicable

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K160503

ITEM	Proposed Device	Predicate Device K160503	Comment
Product code	LHI	LHI	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Regulation Name	Intravascular administration set	Intravascular administration set	Same
Class	II	II	Same
Indications for use	The Vented Vial Transfer Pin is intended for the transfer and mixing of drugs contained in a vial.	The Vented Vial Adapter Transfer Device is intended for the transfer and mixing of drugs contained in a vial.	Same
Configuration	Dual lumen piercing spike. A 0.2μm hydrophobic air filter medium is assembled to the end of air channel.	Vial adapter body contains the dual lumen piercing spike, Assembled 0.2μm hydrophobic air path filter.	Same
material	Acrylonitrile Butadiene Styrene Copolymer(ABS), Polyvinyl chloride(PVC) or ABS, Polytetrafluoroethylene(PTFE), Polypropylene(PP), White color additive, Blue color additive	Polycarbonate, PTFE membrane, Non-woven polyester	Different; See Comment 1
Expiration Date	5 years	3years	Different; See Comment 2
Sterile	Sterile	Sterile	Same
Sterile method	EtO Sterilized	Gamma	Different; See Comment 3

SAL	10^{-6}	10^{-6}	Same
Single use	Yes	Yes	Same
Environment of use	Healthcare facilities or in home environment by the patient or care-giver	Healthcare facilities or in home environment by the patient or care-giver	Same
Body Diameter	Vented Vial Transfer Pin to fit 13mm vials or other equivalent drug vials, Vented Vial Transfer Pin with Security Clip only to fit 13mm vials.	18.5mm to fit 13mm Vials	Different; See Comment 4
Air Filtration	0.2 micron hydrophobic Filter	0.2 micron hydrophobic Filter	Same
Cap Assembly	Assembly Attached Ultrasonically or bonding	Assembly Attached Ultrasonically	Different; See Comment 5
Vial Adapter Fit (Vial Side)	Snap Fit to Vial and "Tight Grip" Feature	Snap Fit to Vial and "Tight Grip" Feature	Same
Piercing Spike	Plastic - Dual Lumen	Plastic - Dual Lumen	Same
Performance Testing	Product Functionality Performance test(ISO8536-4,7.4 and ISO 80369-7), Filter Bursting Pressure(ISO8536-4,7.5), Flow Rate Testing(ISO8536-4,7.10), Cap/valve-housing detachment from body Test(ISO8536-4,7.3), Internal stress level for assembled product (ISO8536-4, 7.13)	Product Functionality Performance test according to IFU, Filter Bursting Pressure, Flow Rate Testing, Cap/valve-housing detachment from body Test, Internal stress level for assembled product.	Same
Biocompatibility	Cytotoxicity: no cytotoxicity per ISO 10993-5	with ISO 10993	Same
	Irritation: no irritation per ISO 10993-10		
	Sensitization: no sensitization per ISO 10993-10		
	Acute systemic toxicity: no acute systemic per ISO 10993-11		
	Pyrogen: no pyrogen per USP		
	Hemolysis: no hemolysis per ASTM F756		

Comment 1

The patient contact materials for the proposed device are different from predicate device. According to guidance, Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the proposed device is external communicating device of Blood path, indirect and limited contact. The Cytotoxicity test, Sensitization test, Irritation test, Acute systemic toxicity test, Pyrogen test, Hemolysis test have been performed for proposed device. Therefore, this material difference does not affect substantially equivalence on safety and effectiveness.

Comment 2

The expiration date for the proposed device is different from predicate device. The proposed devices have been performed 5 years accelerated aging and demonstrated that the aged samples also complied with the requirements of ISO 8536-4 and ISO 80369-7. The ability of immediate package of the proposed device to maintain the device in a sterile state for a period of 5 years has been validated in accordance with ISO 11607 and ISTA 3A. Therefore, this expiration date difference does not affect substantially equivalence on safety and effectiveness.

Comment 3

The sterile method of proposed device is Eto, the sterile method of predicate device is Irradiation. Both of them achieve a Sterility Assurance Level (SAL) of 10^{-6}. Examination of the Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) residuals have met with ISO 10993-7AMD1:2019, this sterilization difference does not affect substantially equivalence on safety and effectiveness.

Comment 4

The body diameter is different between proposed device and predicate device. The proposed device have two specifications, with security clip and without security clip. The body diameter of device with security clip is same with predicate device to fit 13mm vials. The body diameter of device without security clip is added to fit 13mm vials or other equivalent drug vials. The difference does not affect substantially equivalence on safety and effectiveness.

Comment 5

The cap assembly is different between proposed device and predicate device. The proposed device have two method, ultrasonic welding and bonding. The tensile strength of parts have been tested at 15N for 15s. Both of them meet acceptable criteria. The difference does not affect substantially equivalence on safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device with respect to the indications for use, target populations, treatment method, and technological characteristics.