July 21, 2022

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

Re: K220184
Trade/Device Name: Pump Alignment Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 9, 2022
Received: June 22, 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); 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,

CAPT Alan M. Stevens
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)*
K220184

Device Name
Pump Alignment Syringe

Indications for Use *(Describe)*
The Pump Alignment Syringe is intended for use by healthcare professionals for injection of fluids for medical purposes into patients of all ages, including neonates in a controlled manner with compatible infusion pumps. The Pump Alignment Syringe can also be used for manual injection of fluids for medical purposes.

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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Tab 7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K220184

1. Date of Preparation: 06/07/2022

2. Sponsor Identification

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

Establishment Registration Number: 3005670221

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Pump Alignment Syringe

Regulatory Information
Classification Name: Piston Syringe
Classification: II
Product Code:FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

Indications for Use Statement:

The Pump Alignment Syringe is intended for use by healthcare professionals for injection of fluids for medical purposes into patients of all ages, including neonates in a controlled manner with compatible infusion pumps. The Pump Alignment Syringe can also be used for manual injection of fluids for medical purposes.

5. Device Description

The Pump Alignment Syringe is available in various specifications, including 3ml, 5ml, 10ml, 20ml, 30ml and 60ml. The proposed device consists of three components: (1) plunger, (2) piston, (3) barrel. The connector of barrel have two types of luer-lock and luer-slip.

The proposed device is provided sterile. The product is sterilized by Ethylene Oxide Gas 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.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K980987
Product Name: Becton Dickinson Single Use Hypodermic Syringes

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 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
- ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- 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

- USP<788> Particulate Matter in Injections
- ISO 7886-1:2017 Sterile hypodermic syringe for single use- Part 1: Syringes for manual use
- ISO 7886-2:2020 Sterile hypodermic syringe for single use- Part 2: Syringes for use with power-driven syringe pumps
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications -Part 7:Connectors for intravascular or hypodermic applications

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K980987

ITEM	Proposed Device K220184	Predicate Device K980987	Comment
Product code	FMF	FMF	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Regulation Name	Syringe, Piston	Syringe, Piston	Same
Class	II	II	Same
Indications for use	The Pump Alignment Syringe is intended for use by healthcare professionals for injection of fluids for medical purposes into patients of all ages, including neonates in a controlled manner with compatible infusion pumps. The Pump Alignment Syringe can also be used for manual injection of fluids for medical purposes.	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	Same The 510k summary of K980987 indicates that this device can be used with the infusion pump.
Configuration	Piston Plunger Barrel	Piston Plunger Barrel	Same
material	Polypropylene, Polysoprene, Polydimethysiloxane	Plastic, Synthetic rubber, Silicone based stopper lubricant	See Comment 1
Sterile	Sterile	Sterile or non-sterile	See Comment 2

Sterile method	EtO Sterilized	EtO or Irradiation sterilization	See Comment 3
SAL	10^{-6}	10^{-6}	Same
User group	Healthcare professionals	Healthcare professionals	Same
Patient group	All age groups, including neonatal	All age groups, including neonatal	Same
Volume	3ml,5ml,10ml,20ml,30ml,60 ml	1ml,3ml,5ml,10ml,20ml,30 ml and 60ml[1)]	Same
Type of use	Prescription only(Rx)	Prescription only(Rx)	Same
Single use	Yes	Yes	Same
Operation mode	For use with infusion pump or manual use	For use with infusion pump or manual use	Same
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Performance Testing	Conform to: ISO 7886-1 ISO 7886-2 ISO 80369-7	Conform to: ISO 7886-1 ISO 7886-2 6% (Luer) connector	Same
Biocompatibility	Cytotoxicity ISO 10993-5:2009 Third edition	with ISO 10993	Same
	Irritation ISO 10993-10:2010 Third edition		
	Sensitization ISO 10993-10:2010 Third edition		
	Acute systemic toxicity ISO 10993-11:2017 Third edition		
	Pyrogen USP <151> USP41 NF36		
	Hemolysis ASTM F756-17 Third edition		
	Subacute toxicity ISO 10993-11:2017 Third edition		

Note:1)we infer that these sizes of proposed syringe are covered by the 510(k) number K980987 According to the pump user manual (Medfusion 3500 and Alaris 8015), however, these dimensions do not appear in the summary.

Comment 1

Differences in materials between the predicate and subject device were addressed through Biocompatibility Statement and copy of test report.

Comment 2

The subject device is provided sterile only, the predicate device is provided to include sterile and non-sterile.The difference do not affect safety and effectiveness.

Comment 3

The sterile method of subject device is Eto only, the sterile method of predicate device include Eto and Irradiation. The difference do not affect 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.