June 2, 2023

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

Re: K230635
Trade/Device Name: Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 22, 2022
Received: March 7, 2023

Dear Camel Zhou:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.06.02 13:52:41 -04'00'

For CAPT Alan 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230635

Device Name
Pen Needle

Indications for Use *(Describe)*
Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K230635 510(k) Summary

1. Date of Preparation: May 05, 2023

2. Sponsor Identification

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

Establishment Registration Number: 3005670221

Contact Person: Jun Lu
Position: General Manager
Tel: +86-510-86205183
Fax: +86-510-86215183
Email: jun.lu@cainamed.com

3. Designated Submission Correspondent

Ms. Tracy Gong (Primary Contact Person)
Email: tracy.gong@cainamed.com
Mr. Camel Zhou (Alternative Contact Person)
Email: camel.zhou@cainamed.com
Tel: +86-510-86866666-8027
Fax: +86-510-86866666-8009

4. Identification of Proposed Device

Trade Name: Pen Needle

Regulatory Information

Regulation Name: Hypodermic Single Lumen Needle
Device Class: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

Indications for Use Statement:
Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

5. Device Description

The proposed device, Pen Needle, is designed for use with pen injectors for subcutaneous injection of a desired dose of drugs approved for delivery using a pen needle. It is provided sterile, single use.

The proposed device consists of four components, which are 1) Needle Container 2) Needle Shield 3) Needle Tube and 4) Needle Hub. Needle Container, together with Sealed Paper can forming the unit packaging of Pen Needle, that maintains the sterility of Pen Needle. The Needle Hub can be connected screwed onto the pen injectors.

6. Identification of Predicate Device

Predicate Device
510(k) Number: K171982
Product Name: Droplet® Pen Needle

7. Clinical Test Conclusion

Not applicable.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K171982	Comment
Product code	FMI	FMI	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	Same
Classification Name	Hypodermic Single Lumen Needle	Hypodermic Single Lumen Needle	Same
Regulation Class	II	II	Same
Indications for use	Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs	Droplet® Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.	Same
Prescription/ OTC	OTC	OTC	Same
Supplied	Yes	Yes	Same

sterile			
Single use	Yes	Yes	Same
Principle of operation	Manual	Manual	Same
Method of attachment to pen injector	Screw threads	Screw threads	Same
Model	0.18mm(34G) x 4mm TW 0.18mm(34G) x 4mm ETW 0.20mm(33G) x 4mm TW 0.20mm(33G) x 4mm ETW 0.20mm(33G) x 5mm TW 0.20mm(33G) x 5mm ETW 0.20mm(33G) x 6mm TW 0.20mm(33G) x 6mm ETW 0.23mm(32G) x 4mm TW 0.23mm(32G) x 4mm ETW 0.23mm(32G) x 5mm TW 0.23mm(32G) x 5mm ETW 0.23mm(32G) x 6mm TW 0.23mm(32G) x 6mm ETW 0.25mm(31G) x 4mm TW 0.25mm(31G) x 4mm ETW 0.25mm(31G) x 5mm TW 0.25mm(31G) x 5mm ETW 0.25mm(31G) x 6mm TW 0.25mm(31G) x 6mm ETW 0.25mm(31G) x 8mm TW 0.25mm(31G) x 8mm ETW 0.30mm(30G) x 5mm TW 0.30mm(30G) x 5mm ETW 0.30mm(30G) x 6mm TW 0.30mm(30G) x 6mm ETW 0.30mm(30G) x 8mm TW 0.30mm(30G) x 8mm ETW 0.30mm(30G) x 10mm TW 0.30mm(30G) x 10mm ETW 0.33mm(29G) x 8mm TW 0.33mm(29G) x 8mm TW 0.33mm(29G) x 10mm TW 0.33mm(29G) x 10mm TW 0.33mm(29G) x 12mm TW	4mm x 32G 5mm x 32G 6mm x 32G 8mm x 32G 5mm x 31G 6mm x 31G 8mm x 31G 10mm x 29G 12mm x 29G	Different Comment 1

	0.33mm(29G) x 12mm TW		
Biocompatibility	Conform with ISO 10993 standards	Conform with ISO 10993 standards	Same
Sterility	SAL=10^{-6}	SAL=10^{-6}	Same
Sterilization method	EO sterilized	Gamma irradiation	Different Comment 2
Shelf Life	5 year	5 year	Same
Unit Packaging	Polypropylene container with seal made of medical grade paper	Polypropylene container with seal made of medical grade paper	Same
Material	Needle Tube: Medical Grade Stainless Steel Needle Hub, Needle Container, Needle Shield: Plastic resins Lubricant: Medical grade silicone	Needle Tube: Medical Grade Stainless Steel Needle Hub, Needle Container, Needle Shield: Plastic resins Lubricant: Medical grade silicone	Same
Configuration	Needle Tube Needle Hub Needle Container Needle Shield	Needle Tube Needle Hub Needle Container Needle Shield	Same
Performance Testing	Complied with: ISO 11608-2 ISO 9626	Complied with: ISO 11608-2 ISO 9626 ISO 7864	Different Comment 3

Comment 1

The models for proposed device are different from the predicate device. However, this difference is just in dimension. Different gauge, length and wall of needle tube will be selected by users. This difference does not affect intended use and not affect substantially equivalence on safety and effectiveness.

Comment 2

The sterilization method of proposed device is Eto, the sterilization method of predicate device is gamma 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 prolonged exposure devices allowable limits of ISO 10993-7AMD1:2019, this sterilization method difference does not affect substantially equivalence on safety and effectiveness.

Comment 3

Predicate Device have been performed testing according to the requirements of clause 4.6 Freedom from defects (The needle tube shall fulfil the requirements of ISO 7864:1993, 11.3.) of ISO 11608-2:2012, the subject device performed the same testing according to the requirements of clause 5.2.5 Freedom from defects of the updated ISO 11608-2:2022. Although the reference ISO standards are different, but the same tests have been performed. The difference on reference ISO standards does not affect substantially equivalence on safety and effectiveness.

9. Non-Clinical Test

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 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 11608-2:2022 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended pen needles

Biocompatibility

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood path indirect, Prolonged contact (> 24 hours to 30 days). The following endpoints were evaluated:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Subchronic Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemolysis
- Particulate testing per USP <788> Light obscuration method

Sterilization, Shipping and Shelf-Life

The subject device has a 5-year shelf life

- USP-NF <151> Pyrogen Test
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-21 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
- ASTM F1140/F1140M-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- USP-NF <85> Bacterial Endotoxins Test
- ISO 10993-7:2008 AMD.1:2019 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals

- ISTA 3A:2018 Simulated Distribution

10. Substantially Equivalent (SE) Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Pen Needle is substantially equivalent to the Droplet® Pen Needle with respect to the indications for use, target population, treatment method, and technological characteristics.