December 13, 2017

Jiangsu Caina Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai 200120, China

Re: K170846
Trade/Device Name: Disposable Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 9, 2017
Received: November 13, 2017

Dear Ms. Diana Hong:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170846

Device Name

Disposable Insulin Pen Needle

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

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

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K170846

1. Date of Preparation: 12/12/2017

2. Sponsor Identification

Jiangsu Caina Technology Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Subject device

Trade Name: Disposable Insulin Pen Needle
Common Name: Insulin Pen Needle

Regulatory Information

Classification Name: Hypodermic single lumen needle;
Classification: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

Indications for Use:
The Disposable Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Device Description
The subject device, Disposable Insulin Pen Needle, is a single-use device, which is designed for used with a pen injector for the subcutaneous injection of insulin. It consists of needle tube, inner sheath, outer sheath, hub and sealed paper. The hub can be connected screwed onto the insulin pen. The subject device is not intended for neonates, newborn infants or children. The subject device is used in conjunction with following pen injector during clinical use.

K Number	Product Name	Manufacturer
K123766	NovoPen	Novo Nordisk Inc
K142518	HumaPen	Eli Lilly and Company

5. Identification of Predicate Device

510(k) Number: K152824
Product Name: MEDT Pen Needle
Manufacturer: Shandong Caremed Medical Products Co., Ltd.

6. Non-Clinical Test Conclusion

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

- ISO 7864: 1993 Sterile hypodermic needles for single use

- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices
- ISO 11608-2:2012 Needle-based injection systems for medical use- Requirements and test methods-Part 2: Needles
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
- ASTM F88/F88M-09 Standard test method for seal strength of flexible barrier materials
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages
- USP 39-NF 34 <85> Bacterial Endotoxins Test
- ASTM F2096-11 Standard Test Method For Detecting Gross Leak in Medical Packaging by Internal Pressurization (Bubble Test)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

The biocompatibility testing, including cytotoxicity, irritation, sensitization, systemic toxicity and hemolysis were referenced to demonstrate that the patient-contact materials of subject device meets the requirements of following ISO 10993 series standards.

- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity;
- ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2006, Biological evaluation of medical devices Part 11: Tests for systemic toxicity;
- ASTM F756-13, Standard Practice for Assessment of Hemolytic Properties of Materials.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item		Subject device	Predicate Device K152824
Product Code		FMI	FMI
Regulation Number		880.5570	880.5570
Indications for Use		The Disposable Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	The MEDT Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.
∩	Cannula	304 Stainless Steel	304 Stainless Steel

	Hub	Polypropylene	Polypropylene
	Lubricant	Polydimethylsiloxane	Polydimethylsiloxane
	Needle Cap	Polyethylene	Polyethylene
	Needle Hub Protector	Polypropylene	Polypropylene
	Sealed Paper	Paper	Paper
Operation Mode		Manual	Manual
Needle Gauge		29G, 30G, 31G, 32G	29G, 30G, 31G, 32G
Needle Dimension (mm)		0.23×4 0.25×4, 0.25×5, 0.25×6, 0.25×8, 0.30×8, 0.30×10 0.33×12	0.23×4, 0.23×5, 0.23×6, 0.25×4, 0.25×5, 0.25×6, 0.25×8, 0.30×5, 0.30×6, 0.30×8, 0.33×10, 0.33×12
Performance		Comply with ISO 7864, ISO 9626, and ISO 11608-2	Comply with ISO 7864, ISO 9626, and ISO 11608-2
Sterile		EO sterilized, SAL: 10^{-6}	EO sterilized, SAL: 10^{-6}
Single Use		Single use	Single use
Labeling		Conform with 21 CFR 801	Conform with 21 CFR 801
Biocompatibility		Conform with ISO 10993 standards	Conform with ISO 10993 standards

The subject device has eight needle sizes; the predicate device has twelve needles sizes. There are seven needle sizes of subject device are identical to those of the predicate device, only one needle size (0.30×10) of the subject device is different from the predicate device; this size (0.30×10) has same needle gauge as the predicate, but has a longer length than the predicate. The needle size (0.30×10) meets the performance requirements of ISO 7864, ISO 9626 and ISO 11608 standards, and the needle length (10mm) is one common insulin needle length for clinical use, therefore we think the difference on needle length will not raise new problem for the subject device.

All the subject devices are complied with the same performance standards. Through performance bench testing, the subject device has demonstrated that it is substantially equivalent to the predicate.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.