February 18, 2020

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

Re: K192677
Trade/Device Name: Safety Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 27, 2019
Received: January 14, 2020

Dear 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. 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192677

Device Name
Safety Insulin Pen Needle

Indications for Use *(Describe)*
The Safety Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin. The attached safety shield automatically locks after injection and reduces the occurrence of accidental needle sticks from the patient end of the needle.

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 K192677

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

The assigned 510(k) Number: _K192677_

1. Date of Preparation: 2/17/2020

2. Sponsor Identification

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

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

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Safety Insulin Pen Needle
Common Name: Safety insulin needle for single use

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 Safety Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin. The attached safety shield automatically locks after injection and reduces the occurrence of accidental needle sticks from the patient end of the needle.

Device Description
The Safety Insulin Pen Needle consists of hub, spring, needle tube, safety shield, housing, safety seat, outer container and sealed paper. The sharps protection feature can be passively activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The proposed device is not intended for neonates, newborn infants or children. Pen injector compatible with pen needle is provided as follows:

Manufacturer	Pen Injector	510(k) Number
Novo Nordisk Inc.	NovoPen Echo®	K123766
Eli Lily and Company	HumaPen Luxura	K142518

The proposed Safety Insulin Pen Needle 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

510(k) Number: K181447
Trade/Device Name: Safety insulin needle for single use

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications 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 10993-7:2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
- ISO 7864:2016 Sterile hypodermic needles for single use- Requirements and test methods
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 11608-1:2014 Needle-based injection systems for medical use-Requirements and test methods-Part 1: Needle-based injection systems
- ISO 11608-2:2012 Needle-based injection systems for medical use-Requirements and test methods-Part 2:Needles
- ISO 23908:2011 Sharps injury protection-Requirements and test methods- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- USP<85> Bacterial Endotoxins Test
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packing by Visual Inspection
- ASTM F88/F88M-15 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K181447
Product Code	FMI	FMI
Regulation No.	21 CFR 880.5570	21 CFR 880.5570
Class	II	II
Indication for Use	The Safety Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin. The attached safety shield automatically locks after injection and reduces the occurrence of accidental needle sticks form the patient end of the needle.	The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.
Needle gauge	29G, 30G, 31G, 32G	29G, 30G, 31G, 32G, 33G, 34G
Needle length	4mm, 5mm, 6mm, 8mm, 10mm	4mm, 5mm, 6mm, 8mm
Wall type	Thin-walled Extra-thin-walled	Thin-walled Extra-thin-walled
Needle performance	Complied with ISO 7864:2016 ISO 9626:2016 ISO 11608-1:2014 ISO 11608-2:2012	Complied with ISO 7864:2016 ISO 9626:2016 ISO 11608-2
Configuration and material	Needle tube	Needle Tube
	Hub	Hub
	Spring	Spring
	Safety seat	Safety seat
	Seal paper	Sealed paper
	Outer container	Safety protective cover
	Safety shield	Self-destruction seat
	Housing	Hub sheath
Safety feature functions	With safety feature	With safety feature
Biocompatibility		
Cytotoxicity	Biocompatibility is demonstrated	No cytotoxicity

Irritation	by reference device (K170846)	No intracutaneous reactivity
Sensitization		No skin sensitization
Systemic Toxicity		No systemic toxicity
Hemolysis		No hemolysis
Pyrogen		No pyrogen
Single use	Single use	Single use
Sterilization	EO sterilization	EO sterilization
SAL	10^{-6}	10^{-6}
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801
Endotoxin Limit	20 EU per device	20 EU per device

Analysis on the differences between the predicate and proposed device:

Analysis on indications for use:

Both the predicate and proposed device are intended for use with pen injector devices for the subcutaneous injection of insulin. And they have the safety feature to reduce the occurrence of accidental needle sticks. Therefore, although they have different expression on the indication for use, the predicate and proposed device has the same indicatiosn for use.

Analysis on configuration

The proposed device and predicate device have the same configuration; the difference is the naming of each component.

Analysis on needle gauge

The needle gauge of the proposed device is different from the predicate device. However, the needle gauge within the range of predicate device needle gauges.Additionally, the performance of needle has been evaluated and the test results comply with related standards requirements. Therefore, this difference does not affect equivalence of the proposed device and predicate device.

Analysis on needle length

The propose device has an additional 10mm in the needle length, which is outside the range of the predicate device (K181447). However, information provided in the reference device Disposable Insulin Pen Needle (K170846) (Jiangsu Caina Medical Co., Ltd) which validated the 10mm needle length which is also the product of the sponsor has the same needle length as the subject device.

Analysis on safety feature functions

The safety feature functions of predicate device is not exposured in the predicate device's 510(k) summary. ISO 23908 Safety Feature Testing was conducted to compare the needle safety activation force and force to challenge safe mode both on the predicate and proposed device. The test results demonstrated that they have the similar safety feature functions. Therefore, this item is considered to be substantial equivalent.

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.