November 17, 2022

Ningbo Medsun Medical Co., Ltd.
℅ Marvin Li
Consultant
Shanghai Mihe Enterprise Management Consulting Co., Ltd.
Room 313, No. 620 Zhennan Road
(Building 9, Tongji University Science Park), Putuo District
Shanghai, 200331
China

Re: K221178
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: October 18, 2022
Received: October 21, 2022

Dear Marvin Li:

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,

Alan M. Stevens -S3

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221178

Device Name
Disposable Insulin Pen Needle

Indications for Use *(Describe)*
Disposable Insulin Pen Needle(Model CT) : Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.
Disposable Insulin Pen Needle(Model ST) : Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. Additionally, it has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks from the patient end of the needle due to the effect of safe-lock guard.

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.

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K221178

510(k) Summary

1.Date Prepared: November 17th, 2022

2.Submitter

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Date Prepared: November 17th, 2022

3.Device

Trade Name: Disposable Insulin Pen Needle
Common Name: Hypodermic single lumen needle
Classification Name: Needle, Hypodermic, Single Lumen
Regulation Number:21 CFR 880.5570
Regulatory Class: II
Product Code: FMI
Review Panel: General Hospital

4. Predicate device 4.1

Primary Predicate device A
Manufacturer: Jiangsu Caina Technology Co., Ltd.
Device name: Disposable Insulin Pen Needle
510(k) number: K170846
Secondary Predicate device B
Manufacturer: Jiangsu Caina Technology Co., Ltd.
Device name: Safety Pen Needle
510(k) number: K192677

5.Device description

Disposable Insulin Pen Needle, could be divided into Model CT (normal type) and model ST(safety type) according to whether there is sharps protection features. Model CT consists of needle hub, needle container, needle tube, needle shield and seal (dialyzing paper). Model ST consists of needle hub, needle container, protective cap, needle tube, spring, slider,

protective jacket and seal (dialyzing paper). The device is sterilized by EO gas and for single use. The shelf life is 5 years.

Needle tube is fixed in the center of the needle hub with UV glue, the needle tip is protected with needle shield or protective jacket before use, medical dialyzing paper is covered and sealed needle container to maintain sterile of the device. The cartridge end of needle can be inserted into the rubber of insulin pen, meanwhile the needle hub is connected to insulin pen with screw thread to provide sterile fluid path for injection of insulin during use. When Disposable Insulin Pen Needle is connected to insulin pen operates on the principles of common piston syringes. The patient end and the cartridge end of the needle tube are lubricated with silicone oil for ease of injection and rubber penetration.

Model ST has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks from the patient end of the needle due to the effect of safe-lock guard.

6.Indications for use

Disposable Insulin Pen Needle (Model CT): Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

Disposable Insulin Pen Needle (Model ST): Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. Additionally, it has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks from the patient end of the needle due to the effect of safe-lock guard.

7.Comparison of technological characteristics with the predicate device

7.1Comparison between Model CT Disposable Insulin Pen Needle and Predicate Device A

Description	Subject Device (Model CT) (K221178)	Predicate Device A (K170846)	Remark
Proprietary/ trade name	Disposable Insulin Pen Needle	Disposable Insulin Pen Needle	/
Product Code	FMI	FMI	Same
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	Same
Indications for use	Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	The Disposable Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
Prescription/over -the counter use	Over-the counter use	Over-the counter use	Same
Operation Mode	Manual	Manual	Same
Environment of use	Home, Health center	Home, Health center	Same

<table>
<tr><td>Intended users</td><td colspan="2">For self-administration or by a caregiver</td><td colspan="2">For self-administration or by a caregiver</td><td>Same</td></tr>
<tr><td>Hub/needle bond strength</td><td colspan="2">Conform with ISO 11608-2</td><td colspan="2">Conform with ISO 11608-2</td><td>Same</td></tr>
<tr><td>Method of attachment to pen injector</td><td colspan="2">Screw structure, conform with ISO 11608-2</td><td colspan="2">Screw structure, conform with ISO 11608-2</td><td>Same</td></tr>
<tr><td>Needle tip configuration</td><td colspan="2">Tri-bevel edge needle</td><td colspan="2">Tri-bevel edge needle</td><td>Same</td></tr>
<tr><td>Shelf life</td><td colspan="2">5 years</td><td colspan="2">3 years</td><td>Different (Note 1)</td></tr>
<tr><td rowspan="6">Size(s)</td><td>Outer diameter</td><td>Length</td><td colspan="2" rowspan="6">Needle Gauge: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</td><td rowspan="6">Similar (Note 2)</td></tr>
<tr><td>0.33mm</td><td>10mm, 12mm</td></tr>
<tr><td>0.30mm</td><td>5mm</td></tr>
<tr><td>0.25mm</td><td>5mm,6mm,8 mm</td></tr>
<tr><td>0.23mm</td><td>4mm,5mm, 6mm,8mm</td></tr>
<tr><td>0.20mm</td><td>4mm</td></tr>
<tr><td rowspan="8">Configuration and Material</td><td>Needle tube</td><td>Stainless steel SUS304</td><td>Cannula</td><td>304 Stainless Steel</td><td rowspan="8">Similar (Note 3)</td></tr>
<tr><td>Needle hub</td><td>PP</td><td>Hub</td><td>Polypropylene</td></tr>
<tr><td>Needle container</td><td>PP</td><td>Needle Cap</td><td>Polyethylene</td></tr>
<tr><td>Needle shield</td><td>PP</td><td>Needle Hub Protector</td><td>Polypropylene</td></tr>
<tr><td>Lubricant</td><td>Silicon oil</td><td>Lubricant</td><td>Polydimethylsiloxane</td></tr>
<tr><td>Adhesive</td><td>UV glue</td><td>/</td><td>/</td></tr>
<tr><td>Seal</td><td>Medical dialyzing paper</td><td>Sealed Paper</td><td>Paper</td></tr>
</table>

Performance	Meet the requirements of ISO 7864, ISO 9626, ISO 11608-2	Comply with ISO 7864, ISO 9626, and ISO 11608-2	Same
Sterilization	EO Sterilization SAL:10^{-6}	EO sterilized, SAL: 10^{-6}	Same
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Biocompatibility	Meet the requirements of ISO10993 series standards, and the following tests are performed: In vitro cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, subchronic toxicity, particulate matter for injections and pyrogen.	Conform with ISO 10993 standards	Similar (Note 4)
Reuse or single use	Single use	Single use	Same

Note 1: The shelf life of the predicate device A is 3 years. The shelf life of the subject device is 5 years according to the result of accelerated aging test by ASTM F88/F88M-2015, which will not affect the safety and effectiveness of the subject device.

Note 2: The outer diameter (gauge) of the predicate device A is covered by the subject device. The subject device has a 0.20mm(33G) type, while the predicate device A doesn't have. The lengths of the subject device for each outer diameter(gauge) have some differences that are physical, the performance bench testing of needle tube with lengths for subject device are demonstrated to meet the requirements of ISO 11608-2.

Note 3: The configuration and material of the predicate device A are mostly the same as the subject device. For the subject device, the adhesive is UV glue, where the predicate device's adhesive is unknown. UV glue is widely used for Insulin Pen Needle to bond needle hub and needle tube. The safety of UV glue is demonstrated with the biocompatibility of final product.

Note 4: Subject Device has been tested for all required biocompatibility endpoints per ISO 10993.

7.2Comparison between Model ST Disposable Insulin Pen Needle and Predicate Device B

Description	Subject Device (Model ST) (K221178)	Predicate Devices B (K192677)	Remark
Proprietary/ trade name	Disposable Insulin Pen Needle	Safety Insulin Pen Needle	/
Product Code	FMI	FMI	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	Same

Indications for use	Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. Additionally, it has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks from the patient end of the needle due to the effect of safe-lock guard.	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.	Same
Prescription/over -the counter use	Over-the counter use	Over-the counter use	Same
Environment of use	Home, Health center	Home, Health center	Same
Intended users	For self-administration or by a caregiver	For self-administration or by a caregiver	Same

Hub/needle bond strength	Conform with ISO 11608-2		Conform with ISO 11608-2		Same
Method of attachment to pen injector	Screw structure, conform with ISO 11608-2		Screw structure, conform with ISO 11608-2		Same
Needle tip configuration	Tri-bevel edge needle		Tri-bevel edge needle		Same
Shelf life	5 years		3 years		Different (Note 5)
Method of activation for the safety mechanism	Before use, red slider is hidden in the protective cap, needle tip is in protective jacket and seen. In use, protective jacket is pressed down and the needle tip is exposed for injection. After use, protective jacket will rebound and red slider is exposed in the transparent protective jacket. The red slider will be seen by user and indicate that safe-lock guard have be activated. The needle cannot be used again.		Before use, red slider is exposed in the protective cap, needle tip is in protective jacket and seen. In use, protective jacket is pressed down and the needle tip is exposed for injection. After use, protective jacket will rebound and red slider is hidden in the transparent protective jacket. The red slider will be not seen by user and indicate that safe-lock guard have be activated. The needle cannot be used again.		Similar (Note 6)
Design specifications of the safety mechanism	Dimensions	Slider:3.4mm Protective jacket: 10.3mm	Dimensions	unknown	Similar (Note 7)
	Color	Slider:red Protective jacket: colorless	Color	Slider:red Protective jacket: colorless	
	Strength	≤6N	Strength	unknown	

Size(s)	Outer diameter	Length	Needle gauge:29G, 30G, 31G, 32G Needle length:4mm, 5mm, 6mm, 8mm, 10mm	Similar (Note 8)
	0.30mm	5mm,8mm		
	0.25mm	6mm,8mm		
	0.23mm	4mm,8mm		
Wall type	Thin-walled		Thin-walled, Extra-thin-walled	Similar (Note 9)
Configuration and Material	Needle tube	Stainless steel SUS304	Needle tube ,Hub ,Spring, Safety seat, Seal paper, Outer container, Safety shield, Housing	Similar (Note 10)
	Needle hub	PP		
	Protective cap	PP		
	Spring	Stainless steel SUS304H		
	Slider	PP		
	Protective jacket	PP		
	Needle container	PP		
	Lubricant	Silicon oil		
	Adhesive	UV glue		
	Seal	Medical dialyzing paper		
Performance	Meet the requirements of ISO 7864, ISO 9626, ISO 11608-2, ISO 23908		Complied with ISO 7864:2016 ISO 9626:2016 ISO 11608-1:2014 ISO 11608-2:2012	Similar (Note 11)
Sterilization	EO Sterilization SAL:10^{-6}		EO Sterilization SAL: 10^{-6}	Same
Biocompatibility	Meet the requirements of ISO10993 series standards, and the following tests are performed: In vitro cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, subchronic toxicity, particulate matter for injections and pyrogen.		Conform with ISO 10993 standards	Similar (Note 12)
Reuse or single use	Single use		Single use	Same

Sharps injury protection feature	Meet the requirements of safe-lock guard activation and safety overriding/ unlocking force after activation (triggering performance) as per ISO 23908.	With safety feature	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Note 5: The shelf life of the predicate device B is 3 years. The shelf life of the subject device is 5 years according to the result of accelerated aging test by ASTM F88/F88M-2015, which will not affect the safety and effectiveness of the subject device.

Note 6: The method of activation for the safety mechanism is similar between the subject device and predicate device B. In fact, the structure of the safety mechanism is same, but the design of red slider (show the status of the activation) is opposite. Functionality of the safety mechanism has been verified by performing testing per 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.

Note 7: The design specifications of the safety mechanism is similar between the subject device and predicate device B. The color is the same. The dimensions and strength of the subject device is unknown. The design specifications of the safety mechanism of subject device can achieve the function of preventing needlesticks, which is proved by various performance testing.

Note 8: The outer diameter(gauge) and length of the subject device are covered by the predicate device B. The performance bench testing of the outer diameter(gauge) and length for subject device are demonstrated to meet the requirements of ISO 7864, ISO 9626 and ISO 11608-2.

Note 9: The wall type of the subject device are covered by the predicate device B. The predicate device B has extra-thin-walled type, which is a difference. The performance bench testing of the thin-walled for subject device are demonstrated to meet the requirements of ISO 9626. This difference does not impact safety and effectiveness.

Note 10: The configuration of the subject device is mostly the same as the predicate device B, just the name is different. The materials of subject device are common materials and widely used for Insulin Pen Needle in the market, such as stainless steel SUS304, PP, silicon oil, UV glue and Medical dialyzing paper. The safety of materials is demonstrated with the biocompatibility of final product.

Note 11: There are some differences in standards cited for conformance. These differences do not raise new questions of safety and effectiveness.

Note 12: Subject Device has been tested for additional subchronic toxicity and particulate matter for injections compared to the predicate device A.

8.Performance testing summary

Items	Summary
Sterilization	Disposable Insulin Pen Needle is sterilized by EO gas and the sterility assurance level (SAL) is 10^{-6}. The process has been validated according to ISO 11135: 2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices. The maximum EO residual that remain on the device is less than 0.8mg, the maximum ECH residual that remain on the device should be less than 1.8mg according to ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
Product performance	After sterilization, Disposable Insulin Pen Needle meets criteria specified in ISO 11608-2: 2012 Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles; ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods; ISO 7864: 2016 Sterile hypodermic needles for single use – Requirements and test methods and other applicable standards.
Functional compatibility with needle-based injection systems	Selected the insulin pens of commonly used in the U.S. market for compatibility verification. The tests have been completed, the insulin pens which are declared in the label are compatible with the needle.
Transport	The simulated transportation test has been completed according to the requirements of ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. Model CT and Model ST of the products are implemented simulated transportation test. The test result is passed.
Shelf life	The performance of ISO 11608-2, chemical properties, bacterial endotoxin and leakage test (according to ASTM F1929-2015) of Model CT and Model ST have been tested individually before accelerated aging, after 4 years of accelerated aging and 5 years of accelerated aging. According to the accelerated aging test results, the shelf life of the product is determined to be 5 years.
Biocompatibility	Disposable Insulin Pen Needle meets the requirements of ISO 10993 series standards, and the following tests are performed: Cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, subchronic toxicity and material-mediated pyrogenicity. With the requirement of USP <788>, particulate matter for injections also is performed.
Sharps protection features	Model ST product meets the requirements of safe-lock guard activation and safety overriding/unlocking force after activation(triggering performance) as per 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

Clinical simulated use testing	Model ST of Disposable Insulin Pen Needle is a sterile, single-use medical device with an integral sharps injury prevention feature, intended for use with pen injector device for subcutaneous injection of insulin. According to 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 and Guidance for Industry and FDA Staff-Medical Devices with Sharps Injury Prevention Features, we have completed the test of clinical simulated use testing for sharps injury protection. The test results show that Model ST of the product has well sharps injury prevention feature.
The compatible pen injectors	1. NovoPen Echo, K162602, Novo Nordisk Inc. 2. Humapen Luxura, K142518, Eli Lilly and Company 3. Humapen Luxura HD, K100988, Eli Lilly and Company 4. HumanPen Ergo II, K151686, Eli Lilly and Company

Conclusions

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to the predicate device.