September 20, 2023

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
% Alice Huang
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room 8208, Second Floor, No 1399, Jiangyue Road,
Minhang District
Shanghai, 201114
China

Re: K230043
Trade/Device Name: Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 20, 2023
Received: August 23, 2023

Dear Alice Huang:

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: 2023.09.20 11:28:53 -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)*
K230043

Device Name
Insulin Pen Needle

Indications for Use *(Describe)*
The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin. The intended user population of insulin pen needle is for "Adult Use Only" (ages 21yrs old and above).

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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K230043- 510(K) Summary

I. SUBMITTER:

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Summary prepared：September 15, 2023

II. DEVICE

Name of Device:Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Common Name: Insulin Pen Needle for single use
Classification Panel: General Hospital
Regulatory Class: II
Product Code: FMI

III. PREDICATE DEVICE

Primary predicate device: Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type) (K202319)

IV. DEVICE DESCRIPTION

The proposed device, Insulin pen needle and insulin injection pen are use cooperatively to inject insulin into the human body. The Insulin Pen Needle is composed of a needle container, a needle shield, a needle hub, a needle tube.

The insulin pen needle for single use is offered in various gauge sized and length.

The proposed device is available in EO sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Table 1 Specification of Insulin Pen Needle

Designated metric size (mm)	Gauge	Bevel angle		Outer diameter of stylet (mm)		Nominal length of needle tube （mm）						ID (mm)		OD (mm)		Color
		LB	SB	RW	TW	4	5	6	8	10	12	RW	TW	MIN	MAX	
0.18	34G	√	√	/	/	√	√	√	—	—	—	0.064	0.091	0.178	0.191	Orange
0.20	33G	√	√	/	/	√	√	√	√	—	—	0.089	0.105	0.203	0.216	Black
0.23	32G	√	√	/	/	√	√	√	√	√	—	0.089	0.105	0.229	0.241	Deep green
0.25	31G	√	√	/	/	√	√	√	√	√	—	0.114	0.125	0.254	0.267	White
0.30	30G	√	√	0.11	0.13	√	√	√	√	√	√	0.133	0.165	0.298	0.320	Yellow
0.33	29G	√	√	0.11	0.15	√	√	√	√	√	√	0.133	—	0.324	0.351	Red
0.36	28G	√	√	0.11	0.15	√	√	√	√	√	√	0.133	—	0.349	0.370	Blue-green

V. INDICATIONS FOR USE

The Insulin Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The intended user population of insulin pen needle is for “Adult Use Only” (ages 21yrs old and above).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Insulin pen needle and insulin injection pen are use cooperatively to inject insulin into the human body. Additionally, the Insulin Pen Needle is similar to the Insulin Pen Needle (Ordinary Type) (K202319) in regard to insertion, design, size ranges, and material.

Table 2 General Comparison for Insulin Pen Needle

Item	**Proposed Device Insulin Pen Needle**		**Predicate Device Insulin Pen Needle (Ordinary Type)**		**Remark**
K number	TBD		K202319		
Classification	Class II		Class II		Same
Product Code	FMI		FMI		Same
Regulation No.	880.5570		880.5570		Same
Intended use	Insulin pen needle and insulin injection pen are use cooperatively to inject insulin into the human body.		The Insulin Pen Needle (Ordinary Type) is intended for use with pen injector devices for the subcutaneous injection of insulin.		Similar Note 1
Indications for use	The Insulin Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The intended user population of insulin pen needle is for "Adult Use Only" (ages 21yrs old and above).		The Insulin Pen Needle (Ordinary Type) is intended for use with pen injector devices for the subcutaneous injection of insulin.		Similar Note 1
User population	"Adult Use Only" (ages 21yrs old and above)		Adult and Pediatric		Different Note 2
Type-of-use	Prescription only		Over the counter		Different Note 3
Configuration and materials of construction for all components	Needle tube	304 stainless steel	Needle tube	304 stainless steel	Same
	Needle hub	Polypropylene	Needle hub	Polypropylene	
	Needle container	Polypropylene	Outer Sheath	Polypropylene	
	Needle shield	Polypropylene	Inner Sheath	Polypropylene	
	Sealed Paper	Paper	Sealed Paper	Paper	
Operation Mode	For Manual Use Only		For Manual Use Only		Same
Method of attachment to pen injector	Through threaded connection		Through threaded connection		Same

Table 3 Safety and Performance Comparison for Insulin Pen Needle

Item	Proposed Device Insulin Pen Needle	Predicate Device Insulin Pen Needle (Ordinary Type)	Remark
Needle Gauge	28G, 29G, 30G, 31G, 32G, 33G, 34G	29G, 30G, 31G, 32G, 33G	Different Note 4
Needle Length	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	Same
Patient-contact materials			
Needle Tube	304 stainless steel	304 stainless steel	Different Note 5
Needle Hub	PP	Polypropylene	
Lubricant	Silicone oil	MDX4-4159	
adhesive	Uv-curable adhesive	UV glue	
Design specification of the inner sheath (dimensions, color, materials and strength)	14.5*5.8*5.8mm; Transparent color; Polypropylene; Tensile stress at yield>24MPa; Flexural Modulus:>1000MPa; Charpy Notched Impact Strength（23℃）>7kJ/m2	14.3*5.8*5.8mm; Transparent color; Polypropylene; Tensile stress at yield>20MPa; Flexural Modulus:>800MPa; Charpy Notched Impact Strength（23℃）>2.8kJ/m2	Similar
Design specification of the outer sheath (dimensions, color, materials and strength)	30*16*16mm; Transparent color; Polypropylene; Tensile stress at yield>24MPa; Flexural Modulus:>1000MPa; Charpy Notched Impact Strength（23℃）>7kJ/m2	30.3*13.4*13.4mm; Transparent color; Polypropylene; Tensile stress at yield>20MPa; Flexural Modulus:>800MPa; Charpy Notched Impact Strength（23℃）>2.8kJ/m2	Similar
Bond between hub and needle tube	Clause 4.4 of ISO 11608-2:2012; Clause 4.12 of ISO 7864:2016	Clause 4.4 of ISO 11608-2:2012; Clause 4.12 of ISO 7864:2016	Same
Needle tip configuration	Conform with ISO 7864 standards	Conform with ISO 7864 standards	Same
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Intracutaneous reactivity	No Irritation to Skin	No Irritation to Skin	
Skin Sensitization	No Skin Sensitization	No Skin Sensitization	
Acute Systemic Toxicity	No Systemic Toxicity	No Systemic Toxicity	
Pyrogen	No pyrogen	No pyrogen	
Hemolysis	No Hemolysis	No Hemolysis	

Subacute Systemic Toxicity	No Subacute Systemic Toxicity	No Subacute Systemic Toxicity	
Method	EO Sterilized	Irradiation Sterilized	Different Note 6
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf life	5 years	5 years	Same
Label/ Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Discussion in details:

Note 1: Intended Use and Indications for use

Insulin pen needle and insulin pen needle (Ordinary Type) have similar intended use and indications for use, which are intended to be used with Insulin Pen for injection of insulin.

Note 2: User population

The subject device' s user population is covered by the range of user population in the predicate devices. This different will do not raise different questions of safety and effectiveness than the predicate device because all necessary information will be labeled on the packaging and the Instruction for Use.

Note 3: Type-of-use

The subject device' s type-of use is more rigorous than predicate devices. This different will do not raise different questions of safety and effectiveness than the predicate device because all necessary information will be labeled on the packaging and Instruction for Use.

Note 4: Needle gauge

The needle gauge of proposed device is more than that of predicate devices. The difference in needle gauges is made of the same raw materials and the same manufacturing process. Different gauge of needle tube will be selected by users. This difference does not affect intended use and not affect substantially equivalence on safety and effectiveness. In addition, all the needle size of proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantially Equivalency (SE) between the proposed and predicate device.

Note 5: Patient-contact Material

Although the material of proposed and the predicate device is different, the MSDS of Silicone oil and UV-curable adhesive is provided, and the patient-contact material of the proposed device material conforms to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 6: Sterilize Method

Although the Sterilize Method of proposed and the predicate device is different, the sterilize of the proposed device conforms to the ISO 11135:2014 of standards. And the EO residue result was comply with ISO 10993-7 standard requirement. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

VII. PERFORMANCE DATA

The non-clinical tests of the proposed device are tested in conformance with the following standards.

Bench Testing

The chemical performance and physical performance have been tested in compliance with the following standard:

- ISO11608-2: 2012,
- ISO 9626: 2016 and
- ISO 7864: 2016.

The testing results are in conformance with the corresponding standard.

Sterility and Shelf-life

The sterilization process of the proposed device has been validated in compliance with ISO 11135. The EO residual doesn't exceed the limit according to ISO 10993-7. The shelf-life validation study was conducted under the accelerated ageing condition in compliance with ASTM F1980-16 to verify the claimed 5 years shelf-life.

Package Testing

The packaging testing has been performed in compliance with the following FDA recognized consensus standards.

- Vacuum Leak Test, ASTM D3078-02;
- Dye Penetration Test ASTM F1929-15.
- Microbial Barrier Properties Test DIN 58953-6: 2016;
- Seal Strength Test ASTM F88/F88M-21.

Biocompatibility Testing

The biocompatibility evaluation for the insulin pen needles were conducted in accordance with the guidance that is "Use of International Standard ISO 10993-1,"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within Risk Management Process," as

recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemolysis
- Pyrogen
- Subacute Toxicity
- Particulate Matter

Particulate testing was conducted in accordance with USP <788>. The testing results and met the USP acceptance criteria.

Simulated Clinical Use Testing
Simulated clinical use testing of the proposed device has been conducted in compliance with the FDA Guidance for industry and FDA Stuff, Medical Devices with Sharps Injury Prevention Features, August 9, 2005.

Clinical testing
Not Applicable.

VIII. CONCLUSION
The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use, technological characteristics, and performance.