November 12, 2021

Tianjin Huahong Technology Co., Ltd.
Yan Li
Regulatory Affair
A01, Plant B, No. 278, Hangkong Road,
Tianjin Pilot Free Trade Zone
Tianjin, 300308
China

Re: K202319
Trade/Device Name: Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 30, 2021
Received: October 12, 2021

Dear Yan 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,

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)*
K202319

Device Name
Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type)

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

The Insulin Pen Needle (Safety Type) is sterile, single-use safety needle 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.

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510(k) Summary

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

The assigned 510(k) Number: K202319

1. Applicant information

Tianjin Huahong Technology Co., Ltd.

A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park) 300308 Tianjin China

Contact Person: Yan Li

Position: Regulatory Affair

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Email: yan.li@hh-technology.com

2. Date of Preparation: November 10, 2021

3. Identification of Proposed Device

Trade Name: Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type)

Common Name: Insulin Pen Needle

Regulatory Information

Classification Name: Needle, Hypodermic, Single Lumen;

Classification: II;

Product Code: FMI;

Regulation Number: 21 CFR 880.5570;

Review Panel: General Hospital;

4. Identification of Predicate Device

Predicate Device 1

510(k) Number: K181069

Trade Name: Disposable Insulin Pen Needle

Predicate Device 2

510(k) Number: K170988

Trade Name: DropSafe Safety Pen Needle

5. Device Description

The proposed devices, Insulin Pen Needle (Ordinary Type) and Insulin Pen Needle (Safety Type) are single use device, which is designed for used with a pen injector for the subcutaneous injection of insulin. For the safety type, it is designed with a sharp injury prevention feature to minimize the risk from accidental needles sticks. The proposed device is available in 29G, 30G, 31G, 32G and 33G five different specifications with the needle length available in 4mm, 5mm, 6mm, 8mm, 10mm and 12mm for Insulin Pen Needle (Ordinary Type) and 4mm, 5mm, 6mm, and 8mm for Insulin Pen Needle (Safety Type). The product is for single use and provided sterile (Irradiation). The shelf-life of the product is five-years.

6. Indications for Use

The Insulin Pen Needle (Ordinary Type) is intended for use with pen injector devices for the subcutaneous injection of insulin.

The Insulin Pen Needle (Safety Type) is sterile, single-use safety needle intended for use with pen injector devices for the injection of insulin.

7. Comparison of Technological Characteristics

Table 1 General Comparison for Insulin Pen Needle (Ordinary Type)

ITEM	Proposed Device K202319		Predicate Device 1 K181069	
Proprietary/ trade name	Insulin Pen Needle (Ordinary Type)		Disposable Insulin Pen Needle	
Regulation No.	880.5570		880.5570	
Product Code	FMI		FMI	
Class	II		II	
Intended Use	The Insulin Pen Needle (Ordinary Type) is intended for use with pen injector devices for the subcutaneous injection of insulin.		The Disposable Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	
Environment of use	In hospital or in the home environment.		In hospital or in the home environment.	
Type-of-use	Disposable		Disposable	
Configuration and materials of	Needle Tube	Stainless Steel	Needle Tube	Stainless Steel
	Needle Hub	Polypropylene	Hub	Polypropylene

construction for all components	Outer Sheath	Polypropylene	Cup	Polyethylene
	Inner Sheath	Polypropylene	Inner Sheath	Polypropylene
	Sealed Paper	Paper	Sealed Paper	Paper
Operation Mode	For Manual Use Only		For Manual Use Only	
Method of attachment to pen injector	Through threaded connection		Through threaded connection	

Table 2 Safety and Performance Comparison for Insulin Pen Needle (Ordinary Type)

ITEM	Proposed Device K202319	Predicate Device 1 K181069
Needle Gauge	29G, 30G, 31G, 32G, 33G	28G, 29G, 30G, 31G, 32G, 33G
Needle Length	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	4mm, 6mm, 8mm, 12mm
Patient-contact materials		
Needle Tube	Stainless Steel (SUS304)	Stainless Steel
Lubricant	MDX4-4159	Unknown
adhesive	UV glue	Unknown
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
Design specification of the inner sheath (dimensions, color, materials and strength)	14.3*5.8*5.8mm; Transparent color; Polypropylene; Tensile stress at yield>20MPa; Flexural modulus：>800MPa；Charpy Notched Impact Strength（23℃）>2.8kJ/m^2.	Unknown
Design specification of the outer sheath (dimensions, color, materials and strength)	30.3*13.4*13.4mm; Transparent color; Polypropylene; Tensile stress at yield>20MPa; Flexural modulus：>800MPa；Charpy Notched Impact Strength（23℃）>2.8kJ/m^2 .	Unknown
Needle tip configuration	Conform with ISO 7864 standards	Conform with ISO 7864 standards
Cytotoxicity	No Cytoxicity	Conform with ISO 10993 standards
Intracutaneous reactivity	No Irritation to Skin	
Skin Sensitization	No skin sensitization	
Acute Systemic Toxicity	No Systemic Toxicity	
Pyrogen	No pyrogen	

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

Table 3 General Comparison for Insulin Pen Needle (Safety Type)

ITEM	Proposed Device K202319		Predicate Device 2 K170988	
Regulation No.	880.5570		880.5570	
Product Code	FMI		FMI	
Class	II		II	
Intended Use	The Insulin Pen Needle (Safety Type) is sterile, single-use safety needle intended for use with pen injector devices for the injection of insulin.		The DropSafe Safety Pen Needles are sterile, single-use safety needles intended for use with pen injector devices for the injection of drugs.	
Environment of use	In hospital or in the home environment.		In hospital or in the home environment.	
Proprietary/ trade name	Insulin Pen Needle (Safety Type)		DropSafe Safety Pen Needles	
Type-of-use	Disposable		Disposable	
Configuration and materials of construction for all components	Needle Tube	Stainless Steel (SUS304)	Cannula	Medical grade stainless steel
	Needle Hub	Polypropylene	Hub	Plastic resin
	Outer Sheath	Polypropylene	Primary container	Plastic resin
	Inner Sheath	Polypropylene	Slider	Unknown
	Sealed Paper	Paper	Seal	Unknown
	Spring	Stainless Steel (SUS304)	Spring-operated	Stainless steel wire
	Upper Cover	Polypropylene	Needle shield	Plastic resin
Operation Mode	For Manual Use Only		For Manual Use Only	
Method of attachment to pen	Threaded connection method.		Threaded connection method.	

injector		
Safety Feature	Prevent from needlestick	Prevent from needlestick
Method of activation	Trigger shield	Trigger shield

Table 4 Safety and Performance Comparison for Insulin Pen Needle (Safety Type)

ITEM	Proposed Device K202319	Predicate Device 2 K170988
Needle Gauge	29G, 30G, 31G, 32G, 33G	31G
Needle Length	4mm, 5mm, 6mm, 8mm	6mm and 8mm
Patient-contact material		
Needle Tube	Stainless Steel (SUS304)	Medical grade stainless steel
Lubricant	MDX4-4159	Unknown
adhesive	UV glue	Unknown
Bond between hub and needle tube	Drawing force ≥ 22N (29G)；Drawing force ≥ 11N (30G-33G);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
Design specification of the inner sheath (dimensions, color, materials and strength)	21.5*10.7*9.8mm; Transparent color；Polypropylene. Tensile stress at yield>20MPa; Flexural modulus：>800MPa； Charpy Notched Impact Strength（23℃）>2.8kJ/m^2 .	Unknown
Design specification of the outer sheath (dimensions, color, materials and strength)	43.8*18.6*18.6mm; Transparent color；Polypropylene. Tensile stress at yield>20MPa; Flexural modulus：>800MPa； Charpy Notched Impact Strength（23℃）>2.8kJ/m^2 .	Unknown
Design specification of the upper cover (dimensions, color, materials and strength)	30.2*14.6*14.6mm; White; Polypropylene. Tensile stress at yield>20MPa; Flexural modulus：>800MPa； Charpy Notched Impact Strength（23℃）>2.8kJ/m^2 .	Unknown
Needle tip configuration	Conform with ISO 7864 standards	Conform with ISO 7864 standards

Biocompatibility		
Cytotoxicity	No Cytoxicity	Conform with ISO 10993 standards
Intracutaneous reactivity	No Irritation to Skin	
Skin Sensitization	No skin sensitization	
Acute Systemic Toxicity	No Systemic Toxicity	
Pyrogen	No pyrogen	
Hemolysis	No hemolysis	
Subacute Systemic Toxicity	No Subacute Systemic Toxicity	Unknown
Sterilization		
Method	Irradiation Sterilized	Irradiation Sterilized
SAL	10^{-6}	10^{-6}
Endotoxin Limit	20 EU per device	20 EU per device
Shelf life	5 years	Unknown
Label/ Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801

8. Compatible injectors

The Insulin Pen Needle was tested for use with the following pen injectors:

Autopen ® K983974 Owen Mumford, Inc.

Novopen Echo ® K162602 Novo Nordisk Inc.

Humapen and Humapen Ergo K982842 Eli Lilly and Company

Humapen Luxura K142518 Eli Lilly and Company

Humapen Memoir K053563 Eli Lilly and Company

9. Summary of Non-clinical Performance Testing

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

Performance Testing:

- ISO 7864: 2016 Sterile hypodemic 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 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

Biocompatibility Testing:

In accordance with ISO 10993-1, the Insulin Pen Needles are classified as: Externally communicating, indirect blood path with prolonged contact duration (>24 h to 30 d). The following testing was

conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Subacute Toxicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Shipping and Shelf-Life:

The Insulin Pen Needles were sterilized by irradiation to achieve a SAL of 10^{-6}. The radiation source was CO_{60}, and the radiation dose was 25kGy, which was established according to VD_{max} method per ISO11137-2, Sterilization of healthcare products. Radiation. Establishing the sterilization dose. The sterilization was validated according to ISO 11137-2. The Insulin Pen Needles were evaluated for bacterial endotoxin utilizing the USP <85> Limulus Amebocyte Lysate (LAL) method.

- Package integrity testing, after environmental conditioning and simulated transportation was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.
- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
- Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

10. Simulated clinical use testing

A simulated clinical use study was performed on 600 device samples for the Insulin Pen Needle (Safety Type) according to FDA Guidance (Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature) and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

11. Conclusion

The clinical and non-clinical tests demonstrate that the subject device is substantially equivalent to the predicate device.