April 6, 2023

Hantech Medical Device Co., Ltd.
Rachel Jin
Official Correspondent
No 288, Sanheng Road Changhe Industridal Park, Cixi
Ningbo, Zhejiang 315326
China

Re: K222739
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: March 7, 2023
Received: March 7, 2023

Dear Rachel Jin:

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 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)*
K222739

Device Name
Disposable Insulin Pen Needle

Indications for Use *(Describe)*
The Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It can be used by the patient at home or healthcare professionals at medical/health care centers.

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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K222739 510(k) summary

I Submitter

Device submitter: Hantech Medical Device Co., Ltd.
No 288, Sanheng Road Changhe Industridal Park, Cixi 315326, Ningbo
PEOPLE'S REPUBLIC OF CHINA

Contact person:
Name: Arnold Yang
Title: Regulatory Affairs Manager
Phone: +86 18917368988
Fax: +86 574 5899 5557
E-mail: rachel@hantechmedical.com

Date: 03/07/2023

II Device

Trade Name of Device: Disposable Insulin Pen Needle
Common Name: Disposable Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Classification: II
Classification Name: Needle, Hypodermic, Single Lumen
Product code: FMI
Review Panel: General Hospital

III Predicate Devices

Trade name:	Promisemed Insulin Pen Needle
Common name:	Insulin Pen Needle
Classification:	Class II, 21 CFR 880.5570
Product Code:	FMI
Premarket Notification:	K210059
Manufacturer:	Promisemed Hangzhou Meditech Co., Ltd.

IV Device description

The Disposable Insulin Pen Needle consists of a needle tube, a needle hub, a needle container, a needle shield and a seal. The needle tube is a double-ended needle that can be assembled into the needle hub using UV glue. The needle hub has the means of needle assembly attachment to allow it to be screwed onto the pen-injector device. This allows the Non-Patient (NP) end of the needle to penetrate through the rubber septum of the pen injector

cartridge. The Patient and NP ends of the needle are lubricated using silicon oil for ease of injection and rubber septum penetration. The needle shield is assembled over the Patient end of the needle to protect the point from damage and accidental needle sticks. This needle assembly is inserted into a needle container and sealed with a peel-away label to provide a sterile barrier and tamper evidence. The peel-away label is pre-printed with information, which includes the lot number and needle gauge / length. It is supplied with several models. Different models are distinguished by needle gauge and length. The Disposable Insulin Pen Needle is a single-use disposable device and is provided sterile (EO sterilization). It is non-toxic and non-pyrogenic.

Device	Needle length	Needle gauge
Disposable Insulin Pen Needle	4mm, 5mm, 6mm, 8mm, 12mm,	34G, 33G, 32G, 31G, 30G, 29G,

V Indications for use

The Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It can be used by the patient at home or healthcare professionals at medical/health care centers.

VI Comparison of technological characteristics with the predicate devices

The Disposable Insulin Pen Needle has the same intended use, technology, and design as the predicate device and performance specifications are either identical or substantially equivalent to existing legally marketed predicate device. The differences between the Disposable Insulin Pen Needle and predicate device do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K210059	Comments
Indications for use	The Disposable Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It can be used by the patient at home or healthcare professionals at medical/health care centers.	Promisemed Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It is suitable for all age groups including neonate, infant, children and adult, and can be used by the patient at home or healthcare professionals at medical /health care centers.	Same
Product code	FMI	FMI	Same
Regulation	21 CFR 880.5570	21 CFR 880.5570	Same

Device feature	Subject Device		Predicate Device K210059		Comments
number					
Class	CLASS II		CLASS II		Same
Type of Use	Over-The-Counter Use		Over-The-Counter Use		Same
Classification Name	Needle, Hypodermic, Single Lumen		Needle, Hypodermic, Single Lumen		Same
Principle of operation	The user proceeds with inserting the needle into the skin manually. The patient end and the cartridge end of the tube are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.		The user proceeds with inserting the needle into the skin manually. The patient end and the cartridge end of the tube are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.		Same
Specific drug use	Insulin		Insulin		Same
Needle gauge	29G, 30G, 31G, 32G, 33G, 34G		29G, 30G, 31G, 32G, 33G, 34G		
Needle Length	4mm, 5mm, 6mm, 8mm, 12mm		3.5mm±0.4mm (4mm, 5mm, 6mm, 8mm, 12mm)±1.2mm		Substantially equivalent Comment 1
Lubricant	Silicon oil		Silicon oil		Same
Single Use	Yes		Yes		Same
Materials	Needle tube	Stainless Steel (SUS304)	Needle tube	X5CrNi18-10	Substantially equivalent Comment 2
	Needle Hub	Polypropylene	Needle Hub	Polypropylene	
	Needle container	Polypropylene	Needle container	Polypropylene	
	Needle Shield	Polypropylene	Needle Shield	Polyethylene	
	Joint medium	UV glue	Joint medium	UV glue	
	Seal	Dialyzer paper	Seal	Dialyzer paper	
Sterilization	Sterilized by ethylene oxide gas SAL = 10^{-6}		Sterilized by ethylene oxide gas SAL = 10^{-6}		Same
Shelf Life	5 years		5 years		Same
Performance	Complied with ISO 7864, ISO 9626, ISO 11608-2		Complied with ISO 7864, ISO 9626, ISO 11608-2		Same
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity		Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity		Same

Device feature	Subject Device	Predicate Device K210059	Comments
	- Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non-pyrogenic -Subacute Systemic Toxicity: No Subacute Systemic Toxicity	- Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non-pyrogenic	
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

Discussion:

Comment 1

The subject device's needle length is covered by the range of lengths in the predicate device.

Comment 2

The materials of needle tube is different between the subject device and predicate device. The biocompatibility test of the subject device was conducted to demonstrate that the subject device met the biocompatibility requirements. So this difference does not raise any safety and effectiveness problems.

VII Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Disposable Insulin Pen Needle was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “External communication device – Blood path indirect” with a contact duration of “Prolonged (24 hours-30days)”. The following tests were performed, as recommended:

Cytotoxicity	ISO 10993-5: 2009
Skin sensitization	ISO 10993-10: 2010
Hemolysis	ISO 10993-4: 2017
Intradermal reactivity	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017
Subacute Systemic Toxicity	ISO 10993-11: 2017
Particulates	USP 788

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Disposable Insulin Pen Needle is determined based on stability study which includes ageing test.

The testing is performed according to the following standards:

- 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
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance testing

Performance testing is performed according to the following standards:

- ISO 7864:2016 Disposable Medical Safety Hypodermic Needles — Requirements and test methods
- ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices
- ISO ISO 11608-2:2012, Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles

VIII Conclusion

The Disposable Insulin Pen Needle is substantially equivalent to its predicate device (Promisemed Insulin Pen Needle). The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.