March 6, 2023

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

Re: K222672
Trade/Device Name: Disposable Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 7, 2023
Received: February 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 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)*
K222672

Device Name
Disposable Insulin Syringe

Indications for Use *(Describe)*
The product is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

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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Section 5 510(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: +86 189 1736 8988
Fax: +86 574 5899 5557
E-mail: arnoldyang@hantechmedical.com

Date: 09/23/2022

II Device

Trade Name of Device: Disposable Insulin Syringe
Common Name: Disposable Insulin Syringe
Regulation Number: 21 CFR 880.5860
Classification: II
Classification Name: Piston syringe
Product code: FMF
Review Panel: General Hospital

III Predicate Devices

Trade name:	Insulin Syringe
Common name:	Insulin Syringe
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF
Premarket Notification:	K193273
Manufacturer:	Promisemed Hangzhou Meditech Co., Ltd.

IV Device description

The Disposable Insulin Syringe is designed for subcutaneous injection of a desired dose of U-100 and U-40 insulin and has capacity of 0.3mL, 0.5mL, and 1.0mL. The product is a single use, sterile, non-toxic, non-pyrogenic, disposable syringe that consists of a needle, barrel, needle cap, plunger, piston, and plunger cap(only type A). The needle is a single ended lubricated stainless-steel cannula. The needle is covered by a polypropylene needle cap which is placed on the barrel. The barrel is

molded from polypropylene with the exterior permanently marked with the proper scale markings. The piston is attached to the plunger and a Polypropylene plunger cap is placed over the plunger rod(only type A). All products are EO sterilized. The subject device operates on the principle of a piston syringe and has a shelf life of 5 years.

Device	Needle length	Needle gauge	Type
Disposable Insulin Syringe	4mm, 6mm, 8mm, 12mm,	34G, 33G, 32G, 31G, 30G, 29G, 28G, 27G,	A B
Note 1: G in the specification is the gauge specification. Note 2: Type A has the plunger cap; Type B doesn't have the plunger cap.			

V Indications for use

The product is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

VI Comparison of technological characteristics with the predicate devices

The Disposable Insulin Syringe 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 Syringe and predicate device do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K193273	Comments
Indications for use	The product is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Same
Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	CLASS II	CLASS II	Same
Syringe Type	Piston syringe	Piston syringe	Same
Principle of operation	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	Same
Specific drug use	Insulin	Insulin	Same
Volume	0.3ml, 0.5ml, 1.0ml	0.3ml, 0.5ml, 1.0ml	Same
Needle gauge	27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G	28G, 29G, 30G, 31G, 32G	Substantially equivalent

Device feature	Subject Device		Predicate Device K193273		Comments
Needle Length	4mm, 6mm, 8mm, 12mm		6mm, 8mm, 12mm		Comment 1
Needle dimensions	0.18mm, 0.20mm, 0.23mm, 0.25mm, 0.30mm, 0.33mm, 0.36mm, 0.40mm		0.23mm, 0.25mm, 0.30mm, 0.33mm, 0.36mm		
Needle tip configuration	3 bevels		3 bevels		Same
Numbering of scale	At every 5 units for the 0.3mL and 0.5mL syringes, and at every 5 units or 10units for 1.0mL		At every five units for the 0.3mL and 0.5mL syringes, and at every 10units for 1.0mL		Same
Gradations legibility	Legible		Legible		Same
Needle cover color	Red (U-40) and orange (U-100)		Red (U-40) and orange (U-100)		Same
Lubricant composition	Aminofuntional siloxane		Aminofuntional siloxane		Same
Lubricant amount/cm^2	The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube		The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube		Same
Barrel transparency	Transparent		Transparent		Same
Reuse durability	Single Use		Single Use		Same
Hub/needle bond strength	>22N		>22N		Same
Configuration and Materials	Needle	Stainless Steel (SUS304)	Needle	Stainless Steel (SUS304)	Substantially equivalent Comment 2
	Barrel	Polypropylene	Barrel	Polypropylene	
	Plunger	Polypropylene	Plunger	Polypropylene	
	Piston	Polyisoprene rubber	Piston	Polyisoprene rubber	
	Needle cap	Polypropylene	Needle cap	Polyethylene	
	Plunger cap (only type A)	Polypropylene	Plunger cap (only type 8)	Polyethylene	
Sterilization	Sterilized by ethylene oxide gas SAL = 10^{-6}		Sterilized by ethylene oxide gas SAL = 10^{-6}		Same

Device feature	Subject Device	Predicate Device K193273	Comments
Biocompatibility	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	Same
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 gauge, needle length and Needle dimensions are different from the predicate device. This difference does not affect intended use. The differences on needle length and gauge does not raise new questions of safety and effectiveness. In addition, differences in needle length and gauge between the predicate and subject device were addressed through ISO 8537:2016 performance testing.

Comment 2

The materials of needle cap and protective end cap are different between the subject device and predicate device. This difference does not raise any new questions of safety and effectiveness. The biocompatibility test of the subject device was conducted to demonstrate that the subject device met the biocompatibility requirements.

VII Performance data

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

Biocompatibility testing

Biocompatibility of the Disposable Insulin Syringe 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. 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
Subacute chronic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

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 Syringe 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 8537:2016, Sterile single-use syringes, with or without needle, for insulin
- USP <788> Particulate Matter in Injections
- Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes

VIII Conclusion

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