August 10, 2026

HH Global Technology, Inc.
% Ningning Wang
Registered Engineer
Tianjin Huahong Technology Co., Ltd.
A01, Plant B, # 278, Hangkong Rd., Tianjin Pilot Free Trade Zone(Air Port Industrial Park)
Tianjin, 300308, China

Re: K262427
Trade/Device Name: Pen Needle (Ordinary Type I, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Safety Type VII, Ordinary Type IB, Safety type VIII, Safety Type IX, Safety Type X, Ordinary Type XI, Safety Type XII)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 15, 2026
Received: July 16, 2026

Dear Ningning Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for KYRAN R. GIBSON -S

Shruti Mistry
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262427

Please provide the device trade name(s).

Pen Needle (Ordinary Type I, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Safety Type VII, Ordinary Type IB, Safety type VIII, Safety Type IX, Safety Type X, Ordinary Type XI, Safety Type XII)

Please provide your Indications for Use below.

Pen Needles are sterile, single use needles intended for using with pen injector devices for the injection of drug.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) summary

I Submitter

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Preparation date: July 13, 2026

II Proposed Device

Trade Name of Device: Pen Needle (Ordinary Type I, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Ordinary Type IB, Ordinary Type XI, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Safety Type VII, Safety Type VIII, Safety Type IX, Safety Type X, and Safety Type XII)
Regulation description: Hypodermic single lumen needle
Regulation Number: 21 CFR 880.5570
Regulatory Class: Class II
Product code: FMI
Review Panel: General Hospital

III Predicate Device

Predicate Device:
510(k) Number: K252886
Product Code: FMI
Classification: 21 CFR 880.5570
Trade Name: Pen Needle (Ordinary Type I, Ordinary Type VIA, Ordinary Type VIB, Ordinary

Type VIC, Ordinary Type IB, Ordinary Type XI, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Safety Type VII, Safety Type VIII, Safety Type IX, Safety Type X, and Safety Type XII)
Manufacturer: Tianjin Huahong Technology Co., Ltd.

IV Device description

The proposed device is a sterile, single-use Pen Needle intended for use with pen injectors for subcutaneous injection of medication. The Pen Needle consists of a stainless-steel needle cannula attached to a plastic hub and is designed to provide a sterile pathway for medication delivery when used with compatible pen injectors.

The proposed device family includes the following models: **Ordinary Type I, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Ordinary Type IB, Ordinary Type XI, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Safety Type VII, Safety Type VIII, Safety Type IX, Safety Type X, and Safety Type XII.**

The proposed devices have the same intended use, fundamental design features, materials, manufacturing process, sterilization method, and packaging configurations as the predicate device cleared under K252886.

For this Special 510(k) submission, a new needle length specification of **12.7 mm** is added to the **Ordinary Type I Pen Needle models**. The existing needle length options remain unchanged, and no modifications are made to the other Pen Needle models, including the Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Ordinary Type IB, Ordinary Type XI and all Safety Type models. Except for the addition of the 12.7 mm needle length specification for Ordinary Type I models, the proposed device remains identical to the predicate device in terms of design characteristics and technological features.

V Indications for use
Pen Needles are sterile, single use needles intended for using with pen injector devices for the injection of drug.

VI Comparison of technological characteristics with the predicate device
The comparison and discussion between the proposed device and the predicate device are provided in Table 1.

Table 1 Substantial Equivalence Comparison

Item	**Predicate Device** **K252886**	**Proposed device**	**Comments**
Trade Name	Pen Needle (Ordinary Type I, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Ordinary Type IB, Ordinary Type XI, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Safety Type VII, Safety Type VIII, Safety Type IX, Safety Type X, and Safety Type XII)	Pen Needle (Ordinary Type I, Ordinary Type VIA, Ordinary Type VIB, Ordinary Type VIC, Ordinary Type IB, Ordinary Type XI, Safety Type IIA, Safety Type IIB, Safety Type IIIA, Safety Type IIIB, Safety Type IV, Safety Type V, Safety Type VII, Safety Type VIII, Safety Type IX, Safety Type X, and Safety Type XII)	Same
Product Code	FMI	FMI	Same
Regulation number	880.5570	880.5570	Same
Classification Name	Hypodermic Single Lumen Needle	Hypodermic Single Lumen Needle	Same
Device Class	Class II	Class II	Same
Intended Use	Intended for use with pen injector devices for injection of drugs	Intended for use with pen injector devices for injection of drugs	Same
Intended Patient Population	Healthcare personnel, adult patients and adult lay persons	Healthcare personnel, adult patients and adult lay persons	Same

Item	**Predicate Device K252886**	**Proposed device**	**Comments**
Indications for Use	Pen Needles are sterile, single use needles intended for using with pen injector devices for the injection of drug.	Pen Needles are sterile, single use needles intended for using with pen injector devices for the injection of drug.	Same
Prescription/OTC	OTC	OTC	Same
Supplied sterile	Yes	Yes	Same
Sterility	SAL:10^{-6}	SAL:10^{-6}	Same
Sterilization	Irradiation Sterilized	Irradiation Sterilized	Same
Single use	Yes	Yes	Same
Shelf Life	5 years	5 years	Same
Needle Gauge	29G, 30G, 31G, 32G, 33G, 34G	29G, 30G, 31G, 32G, 33G, 34G	Same
Needle Length	3.5mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm	3.5mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm, 12.7mm (12.7 mm added for Ordinary Type I models only)	Different
Materials	Needle Tube: Stainless Steel Needle Hub: Polypropylene (PP) Needle Container: PP Needle Shield: PP/ABS (ABS is only available for safety type)	Needle Tube: Stainless Steel Needle Hub: Polypropylene (PP) Needle Container: PP Needle Shield: PP/ABS (ABS is only available for safety type) Adjusting Sleeve: PP/ABS Lubricant: Medical silicone-based lubricant	Same

Item	Predicate Device K252886	Proposed device	Comments
	Adjusting Sleeve: PP/ABS Lubricant: Medical silicone-based lubricant Jointing medium: UV glue Spring: Stainless steel (Safety type only)	Jointing medium: UV glue Spring: Stainless steel (Safety type only)	
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity - Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute and Subacute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non-pyrogenic	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity - Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute and Subacute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non-pyrogenic	Same
Principle of Operation	Used with a pen injector for injection of drugs	Used with a pen injector for injection of drugs	Same

Item	Predicate Device K252886	Proposed device	Comments
Performance	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Same
Difference Analysis: The proposed device adds a 12.7 mm needle length option for Ordinary Type I Pen Needle models only. Except for this additional needle length, the proposed device remains identical to the predicate device in terms of intended use, design, materials, manufacturing process, sterilization, packaging, and other technological characteristics. The additional needle length has been verified through applicable performance testing and does not raise new questions regarding safety or effectiveness when compared to the predicate device.			

VII Non-Clinical Testing

7.1 Verification and Validation Activities – Design Change

The proposed Pen Needle differs from the predicate device (K252886) by the addition of a new needle length specification of 12.7 mm for the Ordinary Type I Pen Needle models. No changes have been made to the intended use, fundamental operating principle, device design, materials, manufacturing process, sterilization method, packaging configuration, or overall performance specifications of the device.

Design verification and validation activities were conducted to evaluate the impact of the added needle length specification on device safety and performance in accordance with established design control procedures.

7.2 Non-Clinical Testing Overview

Non-clinical testing was performed to support the safety and performance of the proposed device with the new 12.7 mm needle length specification. The testing program included general performance testing, needle dimension and mechanical performance evaluation in accordance with ISO 7864, Pen Needle performance testing in accordance with ISO 11608-2, and accelerated aging evaluation to assess performance throughout the claimed shelf life.

Testing was performed on the proposed Ordinary Type I Pen Needle with the 12.7 mm needle length specification. Both time-zero and after accelerated aging testing were conducted to verify that the modified device maintains its established performance requirements after aging.

All testing was conducted in accordance with internal specifications and applicable standards. Acceptance criteria were established based on the predicate device specifications and applicable regulatory and consensus standards.

7.3 Test Results Summary

All non-clinical verification and validation activities met their predefined acceptance criteria. The results of performance testing, ISO 7864 testing, and ISO 11608-2 testing demonstrated that the proposed Pen Needle with the 12.7 mm needle length specification meets the applicable requirements for needle dimensions, mechanical performance, and functional performance.

The addition of the 12.7 mm needle length specification for the Ordinary Type I Pen Needle models does not adversely affect device performance, sterility assurance, or packaging integrity.

7.4 Conclusions

The results of non-clinical testing demonstrate that the proposed Pen Needle is substantially equivalent to the predicate device (K252886). The addition of a new 12.7 mm needle length specification for the Ordinary Type I Pen Needle models does not alter the device's intended use, fundamental scientific technology, or overall device design.

The design modification does not introduce new risks or raise different questions of safety and effectiveness when compared to the predicate device. The proposed device remains as safe and effective as the legally marketed predicate device.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

Based on the design verification and validation activities and non-clinical performance testing, the proposed Pen Needle was demonstrated to meet all predefined acceptance criteria.

The addition of a 12.7 mm needle length specification for the Ordinary Type I Pen Needle models does not change the intended use, fundamental operating principle, materials, manufacturing process, sterilization method, packaging configuration, or other technological characteristics of the device. The verification and validation results confirm that the design modification does not adversely affect device safety, effectiveness, or performance.

In conclusion, the proposed device is substantially equivalent to the predicate device (K252886). The design modification does not raise different questions of safety and effectiveness when compared to the predicate device, and the proposed device is as safe and effective as the legally marketed predicate device.