January 6, 2026

HH Global Technology, Inc.
℅ Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K252886
Trade/Device Name: Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 4, 2025
Received: December 4, 2025

Dear Maureen O'Connell:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Shruti N. Mistry -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252886

Device Name
Pen Needle

Indications for Use *(Describe)*

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

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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510(k) summary
K252886

I Submitter

HH Global Technology, Inc.
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Buford, GA 30518

Contact person: Grace Hammond
President
Tel.: 770-309-8237
E-mail: grace.hammond@hhglobaltech.com

Preparation date: January 6, 2026

II Proposed Device

Trade Name of Device: Pen Needle
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 and Reference Devices

Predicate Device:
510(k) Number: K220129
Product Code: FMI
Classification: 21 CFR 880.5570
Trade Name: Promisemed X-Safety Pen Needle
Manufacturer: Promisemed Hangzhou Meditech Co., Ltd.

Reference Device:
510(k) Number: K230635
Product Code: FMI
Classification: 21 CFR 880.5570
Trade Name: Pen Needle
Manufacturer: Jiangsu Caina Medical Co., Ltd.

IV Device description

The Pen Needle is a sterile, single use device intended for use with pen injector devices for the subcutaneous injection of drug. The device is available in ordinary and safety configurations.

The intended users include Healthcare personnel, adult patients, and adult lay persons.

The following are the types of needles:

- Ordinary Type I, Ordinary Type IB, Ordinary Type VIA, Ordinary Type VIB, and Ordinary Type VIC needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, and seal paper.
- Safety Type IIA, Safety Type IIB, and Safety Type IIIA needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, needle cover, spring, and seal paper.
- Safety Type IIIB, Safety Type VII, Safety Type VIII, and Safety Type IX needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, needle cover, inner core, spring, and seal paper.
- Safety Type IV needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, needle cover, inner core, rear inner core, spring, and seal paper.
- Safety Type V and Safety Type X needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, needle cover, inner core, rear needle shield, spring, rear spring and seal paper.
- Ordinary Type XI needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, adjusting sleeve and seal paper.
- Safety Type XII needle consists of needle hub, double-ended needle tube, which is bonded with the needle hub with joining medium, needle container, needle shield, needle cover, inner core, rear needle shield, adjusting sleeve, spring, rear spring and seal paper.

The needle shield and rear needle shield provide physical protection to the needle tube before and after use. The needle container together with seal paper forms the primary sterile barrier system and protects the needle hub. The hub is designed to be securely screwed onto the needle-based injection system (e.g. pen injector) for the subcutaneous injection of drug.

The product is individually packaged and sterilized by irradiation to achieve a sterility

assurance level (SAL) of 10^{-6}. It is intended for single use only.

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 and reference devices

The comparison and discussion between the Subject devices and the predicate device are provided in Table 1.

Table 1 Substantial Equivalence Comparison

ITEM	Subject Device	Predicate Device K220129	Comments
Trade Name	Pen Needle	Promisemed X-Safety Pen Needle	Different trade names; no impact on safety or effectiveness.
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	N/A Patient population not described in indications for use statement or 510(k) Summary	The predicate 510(k) summary does not specify intended users. The subject device's stated user population is consistent with the intended users of pen injectors for subcutaneous drug injection and does not change the intended use or raise new or different questions of safety or effectiveness.

ITEM	Subject Device	Predicate Device K220129	Comments
Indications for Use	Pen Needles are sterile, single use needles intended for using with pen injector devices for the injection of drug.	Promisemed X-Safety Pen Needle is intended for use with needle based injector for the injection of drugs.	Same
Prescription/OTC	OTC	OTC Prescription	Different. OTC use for the subject device represents a subset of the predicate clearance. This does not raise new or different questions of safety or effectiveness.
Supplied sterile	Yes	Yes	Same
Sterility	SAL:10^{-6}	SAL:10^{-6}	Same
Sterilization	Irradiation Sterilized	EO Sterilization	Different. The subject device is sterilized by irradiation in accordance with ISO 11137 and achieves a sterility assurance level (SAL) of 10^{-6}, which is equivalent to the predicate device. The difference in sterilization method does not raise new or different questions of safety or effectiveness.
Single use	Yes	Yes	Same
Shelf Life	5 years	5 years	Same
Needle Gauge	29G, 30G, 31G, 32G, 33G, 34G	29G, 30G, 31G, 32G	Different. Needle gauges 29G-32G are the same as the predicate device. The 33G and 34G gauges are supported by reference device K230635 and verified through performance testing.

ITEM	Subject Device	Predicate Device K220129	Comments
			These differences do not raise new or different questions of safety or effectiveness.
Needle Length	3.5mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm	4mm, 5mm, 6mm, 8mm	Different. Needle lengths of 4mm, 5mm, 6mm and 8mm are the same as the predicate device. Needle lengths of 10mm and 12mm are supported by reference device K230635. The 3.5mm needle length which is shorter than both the predicate and reference devices, was evaluated through performance testing and demonstrated comparable performance to other lengths. These differences do not raise new or different questions of safety or effectiveness.
Materials	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 Jointing medium: UV glue	Needle Tube: 304 Stainless steel X5CrNi18-10 Needle Hub: Polypropylene (PP) Container: PP Trigger Spring/Posterior spring: Stainless steel Lubricant: Silicone oil	Different. While some materials are the same as the predicate device (stainless steel and polypropylene), additional materials are used in the subject device. Biocompatibility testing was performed in accordance with ISO 10993-1 and demonstrated that the subject device is biocompatible. These material differences do not raise new or different

ITEM	Subject Device	Predicate Device K220129	Comments
	Spring: Stainless steel (Safety type only)		questions of safety or effectiveness.
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
Performance	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Same

The predicate device was cleared in K220129, and the reference device was cleared under K230635. The devices have the same intended use and similar technological characteristics,

with only minor differences as identified in the table above. The subject device met the same non-clinical performance testing requirements as the predicate, and biocompatibility testing conducted in accordance with ISO 10993 demonstrated compliance with the same acceptance criteria. The reference device was used to support substantial equivalence for differences in needle gauge and needle length.

VII Compatible injectors

Universal design for compatibility with most pen injector devices available on the market that comply with ISO 11608-1. Specifically:
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

VIII Non-Clinical Testing

Non-clinical testing was conducted to verify that the proposed device meets all design specifications and is substantially equivalent to the predicate device. The test results demonstrate that the proposed device complies with the following standards:

Performance Testing:

- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices
- ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- ISO 11608-2:2022 Needle-based injection systems for medical use Requirements and test methods Part 2: Double-ended pen 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
- FDA Guidance- Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

Biocompatibility Testing:

In accordance with ISO 10993-1, the Pen Needles are classified as: Externally communicating, indirect blood path with prolonged contact duration (>24 h to 30 d). Biocompatibility testing appropriate for this classification was conducted, including cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, subacute/subchronic toxicity and hemocompatibility.

Sterility, Shipping and Shelf-Life

The Pen Needles were sterilized by irradiation to achieve a SAL of 10^{-6}. The radiation dose of 25kGy was established using the VD_{max} method in accordance with ISO11137-2, and sterilization validation was conducted per ISO 11137-2. Bacterial endotoxin testing was performed using the USP <85> Limulus Amebocyte Lysate (LAL) method.

- Package integrity testing, including environmental conditioning and simulated transportation, was conducted on the final, packaged, and sterile devices and demonstrated adequate protection of the product and maintenance of sterility.
  Sterile Barrier Packaging Testing included:
  - Seal strength (ASTM F88/F88M-21)
  - Dye penetration (ASTM F1929-15)
  - Visual Inspection (ASTM F1886/F1886M-16)

A shelf life of 5 years was validated using the FDA recognized standard ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Simulated Clinical Use

A simulated clinical use study was conducted on 600 device samples of the Pen Needle (safety configuration) in accordance with FDA guidance for medical devices with sharps injury prevention features and ISO 23908:2011. The study evaluated the safety mechanism of the proposed device and demonstrated that all pre-established acceptance criteria were met.

IX Conclusion

The performance testing demonstrates that the proposed device is as safe and effective as the predicate device. Therefore, the proposed device is substantially equivalent to the predicate device.