



November 21, 2025

Terumo Corporation
% Brian Byrd
Regulatory Affairs Specialist II
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K250700
Trade/Device Name: Pen Injector Needle 32.5
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 7, 2025
Received: October 21, 2025

Dear Brian Byrd:

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

Indications for Use

510(k) Number (if known)
K250700

Device Name
Pen Injector Needle 32.5

Indications for Use (Describe)

The Pen Injector Needle 32.5 is indicated for use with a pen injector device for patients who require the subcutaneous injection of drugs including insulin and human growth hormone as a therapy.

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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K250700 510(k) SUMMARY

A. SUBMITTER INFORMATION (807.92(a)(1))

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Date prepared: November 12, 2025

B. DEVICE NAME (807.92(a)(2))

<i>Proprietary Name:</i>	Pen Injector Needle 32.5
<i>Common Name:</i>	Pen Needle
<i>Classification Name:</i>	Hypodermic single lumen needle
<i>Classification Panel:</i>	General Hospital
<i>Regulation:</i>	21 CFR 880.5570
<i>Product Code:</i>	FMI
<i>Classification:</i>	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is:

K140516 – Terumo Pen Injector Needle 34, manufactured by Kofu Factory of Terumo Corporation.

D. REASON FOR 510(k) SUBMISSION

The Pen Injector Needle 32.5, a hypodermic needle manufactured by Kofu Factory of Terumo Corporation, the design of the device is the same as the Pen Injector Needle 34 made by Kofu Factory of Terumo Corporation under K140516.

This Traditional 510(k) is being submitted for Pen Injector Needle 32.5 for the purposes of establishing substantial equivalence to a legally marketed predicate device.

E. DEVICE DESCRIPTION (807.92(a)(4))

The Pen Injector Needle 32.5 consists of a cannula, needle hub, inner needle cap, outer needle case and seal film. The outer needle case and seal film function as the primary packaging and maintain the sterility when unopened.

The Pen Injector Needle 32.5 is a manually operated, disposable device intended for single use only. The device is individually packaged and sterilized by electron beam. The primary package consists of an outer needle case and sealing film.

The cannula is made of stainless steel and it is Thin Walled. The cannula remains 32.5G

throughout the needle length, as a straight hypodermic needle. The cannula is pointed at both the patient interface end, for injection into the patient's body tissue, and the cartridge interface end, to puncture the cartridge for drug delivery.

The Pen Injector Needle 32.5 is available in different needle lengths. The length of the needle patient side (from the glue mount on the hub to the tip of the patient interface end) ranges from 4 mm (5/32") to 8 mm (5/16"). The patient interface end (needle tip) features a 3-bevel, asymmetrical needle edge.

The cartridge interface end is attached to a plastic hub (needle hub) which screws onto a compatible pen injector (not supplied with this device). The length of the needle cartridge side is 6.5 mm (1/4"). The patient interface end (needle tip) is covered by a white plastic needle protector cap (inner needle cap) which is then covered by a clear plastic outer case (outer needle case).

The Pen Injector Needle 32.5 is intended to be used by both trained healthcare professionals in a healthcare facility and layperson in a home.

F. INDICATIONS FOR USE (807.92(a)(5))

The Pen Injector Needle 32.5 is indicated for use with a pen injector device for patients who require the subcutaneous injection of drugs including insulin and human growth hormone as a therapy.

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

A comparison of the technological characteristics is summarized in Table 1 below.

Table 1: Summary of Comparative Information

Device Characteristic	Subject Device: Pen Injector Needle 32.5, K250700	Predicate: Terumo Pen Injector Needle 34, K140516
Manufacturer	Kofu Factory of Terumo Corporation	Same
Intended Use	This product is intended to inject fluids into parts of the body below the surface of the skin.	Same
Indications for Use	This product is indicated for use with a pen injector device for patients who require the subcutaneous injection of drugs including insulin and human growth hormone as a therapy.	This product is indicated for use with a pen injector device for the subcutaneous injection of drugs, including insulin.
Prescription and/or OTC	Both	Same
Operation Principle	Manual	Same
Design / Construction	<ul style="list-style-type: none"> This device consists of a Cannula, Hub, Cap, Case, and Seal film. 	Same
Materials	<ul style="list-style-type: none"> Cannula with Lubricant: Stainless steel with Silicone oil Needle Hub: Polypropylene Inner Needle Cap (Needle Protector Cap): High density polyethylene Outer Needle Case: Polypropylene Seal Film: Synthetic resin impregnated kraft paper Adhesive: UV adhesive (Polyacrylate) 	Same
Package	<ul style="list-style-type: none"> Unit Box (8 pcs, 12 pcs, 100 pcs) Intermediate Box (8 and 12 pcs) Shipping Box 	<ul style="list-style-type: none"> Unit Box (for 100 pcs) Shipping Box
Specifications	Cannula Gauge: 32.5G Needle Length: <ul style="list-style-type: none"> Patient Side (mm): 4, 6, 8 Cartridge Side (mm): 6.5 	Cannula Gauge: 34G Needle Length: <ul style="list-style-type: none"> Patient Side (mm): 4 Cartridge Side (mm): 6.5



Device Characteristic	Subject Device: Pen Injector Needle 32.5	Predicate: Terumo Pen Injector Needle 34, K140516
	Cannula Outer Diameter (mm): 0.22 (32.5G) Cannula Inner Diameter (mm): 0.105 Cannula Wall Thickness: Thin Wall Cannula Shape: Straight Tip Configuration: <ul style="list-style-type: none"> • Patient Side Asymmetrical, 3-bevel • Cartridge Side: Standard, Single bevel 	Cannula Outer Diameter (mm): 0.33 (29G) > 0.18 (34G) Double Tapered Design Cannula Inner Diameter (mm): 0.064 at distal tip (patient interface end)* Cannula Wall Thickness: Normal Wall Cannula Shape: Tapered Tip Configuration: <ul style="list-style-type: none"> • Patient Side Asymmetrical, 3-bevel • Cartridge Side: Bent (Eccentric)
Sterilization	Electron Beam (validated in accordance with ISO 11137 to achieve SAL 10 ⁻⁶)	Same
Shelf Life	5 years (60 Months)	Same

*The I.D. tapers like the O.D. of the device. The measurement point of the I.D. is the distal portion of the needle. The wall thickness of the cannula remains uniform (0.043 + 0.002 mm) throughout.

Note: The indications for use of the K140516 cleared product is essentially the same as the subject device except for the inclusion of the human growth hormone clarification and the purpose for injection of drug. The human growth hormone clarification was added because the predicate device was not labeled as compatible with a pen injector device that delivered human growth hormone. The subject device has been confirmed compatible with a pen injector that is used to deliver human growth hormone, so the indications for use for the subject device included this update to further clarify the type of drug. The purpose of the drug delivery has been clarified to state “as a therapy” to indicate a therapeutic purpose for injection.

Any differences of specifications (Cannula Gauge, Patient Side Needle Length, Cannula Outer Diameter, Cannula Inner Diameter, Cannula Wall Thickness, Cannula Shape, Cartridge Side Tip Configuration, Box Configurations) from Predicate K140516 do not raise any new issues in the device safety or effectiveness of the subject device Pen Injector Needle 32.5 when compared to the predicate device as determined through

design verification activities.

H. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the Pen Injector Needle 32.5 met the predetermined specifications throughout the shelf life, verify conformity to the applicable parts of ISO standards, and demonstrate substantial equivalence to the predicate device. No new issues of safety and effectiveness were raised with the testing performed when compared to the predicate device. The following performance tests were performed:

Table 2: Performance Tests

Test	Standard	Result
Surface Finish Cleanliness Limits for acidity and alkalinity Dimensions Stiffness Resistance to breakage Resistance to corrosion	ISO 11608-2:2022, ISO 9626 Second edition 2016	Meets standard.

Dimensions for double-ended pen needle assembly Flow rate through needle lumen Bond between hub and needle tube Needle points Coring Freedom from defects Dislocation of measuring point at patient end Functional compatibility with NISs Ease of assembly and disassembly	ISO 11608-2:2022 ISO 11608-3:2022	Meets standard.
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Testing per ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods was covered by the standards in the table above.

No deviations from recognized consensus ISO standards were identified in the testing to standards.

Additionally, performance testing other than to the above ISO Standards was performed on the device to verify the modified device against the current. The device complies with the acceptance criteria established based on the predicate:

Table 3: Additional Performance Tests

Performance Test	Results
Penetration resistance	Meets acceptance criteria
Cap-hub Fitting Strength	Meets acceptance criteria
Seal Film Fitting Strength	Meets acceptance criteria

Performance testing demonstrates that the Pen Injector Needle 32.5 conforms to the recognized consensus ISO standards, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout the shelf life.

Biocompatibility

In accordance with ISO 10993-1, the Pen Injector Needle 32.5 is classified as: Externally Communicating Device, Indirect Blood Path, Prolonged Exposure (>24 hours to 30 days). The finished device's blood/body contacting parts were tested in accordance with the FDA guidance issued on September 8, 2023 titled *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process."*

Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Table 4: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Systemic Toxicity (Acute)
Pyrogenicity
Subacute/Subchronic Toxicity
Hemolysis
Physicochemical Profile (Physicochemical, FT-IR and Particulates)
Accelerated-aged (5 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (Physicochemical, FT-IR and Particulates)

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11137 *Sterilization of health care products - Radiation*. The Pen Injector Needle 32.5 is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, and it was determined that there were no new issues of safety or effectiveness when compared to the predicate device.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, the Pen Injector Needle 32.5, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the primary predicate device K140516 – Terumo Pen Injector Needle 34 manufactured by Kofu Factory of Terumo Corporation.