April 4, 2025

Terumo Europe N.V.
Liesbeth Decoster
Regulatory Affairs Manager
Interleuvenlaan 40
Leuven, 3001
Belgium

Re: K243581
Trade/Device Name: K-Pack Enhance Needle (KH-2713RBBTC and KH-2913RBBTC)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 4, 2025
Received: March 4, 2025

Dear Liesbeth Decoster:

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)*
K243581

Device Name
K-Pack Enhance Needle (KH-2713RBBTC and KH-2913RBBTC)

Indications for Use *(Describe)*
The K-Pack Enhance Needle a sterile, hypodermic needle, for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The K-Pack Enhance Needle is for general application - for injection of fluids or withdrawal of fluids.

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.

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Terumo Europe NV

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 12 11
Fax: +32 16 40 02 49

www.terumo-europe.com

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

1. Submitter Information (*807.92(a)(1)*)

Prepared for:	TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM
Prepared by/Contact person:	Mrs. L. Decoster – Regulatory Affairs Manager Tel. (+32) 16 38 13 02 Fax (+32) 16 40 02 49
Date prepared:	April 4, 2025

2. Device Name (*807.92(a)(2)*)

Proprietary Name:	K-Pack Enhance Needle
Common Name:	K-Pack Enhance Needle
Classification Name:	Hypodermic Single Lumen Needle
Classification Panel:	General Hospital
Regulation:	21CFR, Section §880.5570
Product Code:	FMI (Needle)
Classification:	Class II

3. Predicate Devices (*807.92(a)(3)*)

The legally marketed device to which substantial equivalence is claimed:

- K-Pack II Needle 27G x 1/2” Thin Wall (K110850) manufactured by Terumo Europe N.V.

4. Reason for 510(k) Submission

This premarket notification [510(k)] is being submitted for the K-Pack Enhance Needle to provide supporting information that the proposed device is substantially equivalent to the following devices:

- K-Pack II Needle 27G x 1/2” Thin Wall (K110850) manufactured by Terumo Europe N.V.

5. Device Description (*807.92(a)(4)*)

Principle of Operation Technology

The K-Pack Enhance Needle is operated manually or by manual process.

Design/Construction

The K-Pack Enhance Needle is a sterile hypodermic needle for single use consisting of a stainless steel cannula with nominal outside diameter of 0.33 mm or 0.40 mm and a length of 12 mm. The cannula is sharpened at one end and has 45° cut at the other end, which is joined to a female luer connector (hub) made of polycarbonate (PC) designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. The K-Pack Enhance Needle is packed in a hard plastic container (cap and case) made of polypropylene and sealed with a label. The case serves as needle protector. The needle is non-toxic, nonpyrogenic and sterilized by ethylene oxide.

Materials

A list of components and their raw materials is provided in Table 1.

Table 1 - List of Components and their Raw Materials

Component/Part	Material
Cannula	Stainless Steel
Hub	Polycarbonate + Color Masterbatch
Adhesive	Acrylic Adhesive (UV cured)
Lubricant	Substituted Polydimethylsiloxane
	Polydimethylsiloxane
Case	Polypropylene
Cap	Polypropylene

Specifications

Table 2 shows the product codes, needle gauge and needle length.

Table 2 - Product Specifications

PRODUCT CODE	NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL	CANNULA WALL
KH-2713RBBTC	27G – 0.40 mm	½"– 12 mm	Long (regular) bevel	Thin
KH-2913RBBTC	29G – 0.33 mm	½"– 12 mm	Long (regular) bevel	Thin

6. Indications for Use (*807.92(a)(5)*)

The K-Pack Enhance Needle a sterile, hypodermic needle, for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The K-Pack Enhance Needle is for general application - for injection of fluids or withdrawal of fluids.

7. Substantial Equivalence Comparison (807.92(a)(6))

The K-Pack Enhance Needle (KEN), manufactured by Terumo Europe, being the subject of this 510(k), is substantially equivalent to its predicate device:

- K-Pack II Needle 27G x 1/2" Thin Wall (K110850) manufactured by Terumo Europe N.V.

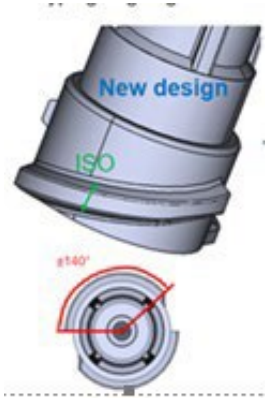
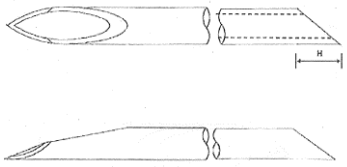
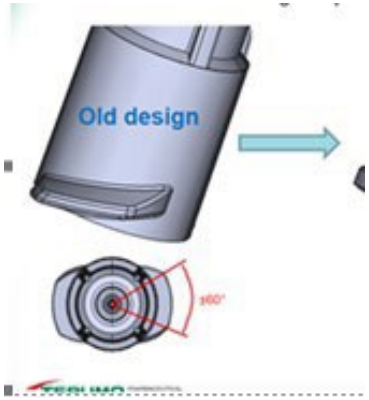
The similarities and differences are summarized below.

Table 3 - Intended Use/Indications for Use

Characteristics	Subject Device: K-Pack Enhance Needle 27G x ½ " TW 29G x ½" TW	Predicate device: K-Pack II Needle 27G & 30G Thin Wall (K110850)	Comments
Intended Use/Indications for Use	The K-Pack Enhance Needle a sterile, hypodermic needle, for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The K-Pack Enhance Needle is for general application - for injection of fluids or withdrawal of fluids.	The 27G & 30G Thin Wall K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	Identical
Prescription or OTC (over the counter)	Prescription	Prescription	Identical

Table 4 - Technological characteristics

Characteristics	Subject Device: K-Pack Enhance Needle 27G x ½“ TW 29G x ½” TW	Predicate device: K-Pack II Needle 27G & 30G Thin Wall (K110850)	Comments
Manufacturer	Terumo Europe N.V.	Terumo Europe N.V.	Identical
Materials	Cannula – Stainless Steel Hub – Polycarbonate/ Masterbatch Adhesive – Acrylic Glue Lubricant – Silicone (Polydimethylsiloxane)	Cannula – Stainless Steel Hub - Polypropylene/ Masterbatch Adhesive – Epoxy Glue Lubricant – Silicone (Polydimethylsiloxane)	SE Both the subject and predicate devices use the same type of stainless steel for the cannula and silicone (polydimethylsiloxane) for the lubricant. The predicate device uses epoxy glue as adhesive and the subject device uses acrylic glue as adhesive. The adhesive has only indirect patient contact (contact with fluids to be injected). The hub of the predicate device is made of polypropylene while the hub from the subject device is made of polycarbonate being also the carrier of the color masterbatch from the same material. The materials introduced with the subject device comply with the required internal specifications (with reference to standards and/or guidance if applicable) and applicable legislation and have passed all necessary tests during incoming inspection. Biocompatibility testing on the finished device supports the adequacy of the selected materials.
Design	Design of the hub:	Design of the hub:	SE

Characteristics	Subject Device: K-Pack Enhance Needle 27G x ½“ TW 29G x ½” TW	Predicate device: K-Pack II Needle 27G & 30G Thin Wall (K110850)	Comments
	 Cannula in hub - With 0.5mm protusion - Back cut = 45° 	 Cannula in hub - Without 0.5mm protusion - Straight back cut	Design of the hub is in accordance with ISO 80369-1:2018 and ISO 80369-7:2021. Cannula is in compliance with ISO 9626:2016.
Specifications	K-Pack Enhance, 27G Needle: 27G x ½” 0.4 mm x 12 mm Thin Wall Regular Bevel Short case	K-Pack II, 27G Needle: 27G x ½” 0.4 x 12 mm Thin Wall Regular Bevel Short case	SE Identical for K-Pack Enhance Needle 27G x ½“ TW. Difference in gauge size for K-Pack Enhance Needle 29G x ½“ TW. Specifications are in accordance with ISO 7864.

Characteristics	Subject Device: K-Pack Enhance Needle 27G x ½“ TW 29G x ½” TW	Predicate device: K-Pack II Needle 27G & 30G Thin Wall (K110850)	Comments
	K-Pack Enhance, 29G Needle: 29G x ½” 0.33 x 12 mm Thin Wall Regular Bevel Short case		
Principle of Operation	Manual	Manual	Identical. Manual use in accordance with ISO 7864. Connection with syringes in accordance with ISO 80369-7.
Unit packaging	Hard cap and case	Hard cap and case	Identical
Sterilization	EO to SAL 10^{-6}	EO to SAL 10^{-6}	Identical. Sterilization validation in accordance with ISO 11135:2014. Residual EO and ECH in accordance with ISO 10993-7:2008 Second edition.
Shelf life	5 years	5 years	Identical

Substantial Equivalence Discussion

- There are no differences in intended use and indications for use between the subject device and the predicate device.
- Subject device has different materials of construction in its hub and adhesive. Biological evaluation has been performed in accordance with ISO 10993-1:2018 to demonstrate the material differences do not raise new or different questions of safety and effectiveness as compared to the predicate device.
- Subject device has a different hub and cannula design. The subject device has both a 27G and 29G cannula model compared to the predicate device with includes a 27G and 30G cannula. In addition, the cannula of the subject device has a 45° back-end cut, whereas the cannula of the predicate device has a straight back-end cut. The 45° back-end cut helps in ensuring an easy fluid passage and a homogenous flow. Design verification has been evaluated according to ISO 7864:2016, ISO 9626:2016 and ISO 80369-7:2021. The same standards were utilized for the predicate device to demonstrate performance. Hence, the differences in technological characteristics of the subject device compared to the predicate do not raise new or different questions of safety and effectiveness.

8. Non Clinical Test (807.92(b)(1))

Performance

The design of the K-Pack Enhance Needle has been validated by Terumo Europe N.V. in accordance with the Design Control Requirements and recognized consensus standards that have been established for hypodermic needles under FDA product code FMI and 21CFR Section 880.5570:

ISO 7864:2016 “Sterile hypodermic needle for Single use”

ISO 9626:2016 ”Stainless steel needle tubing for the manufacturing of medical devices”

ISO 80369-7: 2021 “Small bore connectors for liquids & gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

ISO 6009:2016 “Hypodermic needles for single use — Colour coding for identification”

ISO 11607-1:2019 “Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems”

USP <788> Particulate matter in injections

USP <71> Sterility test

Biocompatibility

The K-Pack Enhance Needles are categorized following the definitions in ISO 10993-1:2018 as external communicating devices that can contact tissue or that can indirectly contact the blood path up to 24 hours (limited exposure).

The biological evaluation for the K-Pack Enhance Needle has been performed taking into consideration the materials of construction and manufacturing process. The raw materials used for the manufacturing of the K-Pack Enhance Needle were carefully selected and consequently the chosen materials are suitable to be used for production of this product for human use. The raw materials comply with the required internal specifications (with reference to standards and/or guidance if applicable) and applicable legislation and have passed all necessary tests during incoming inspection.

Moreover, considering FDA Guidance document: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing within a risk management process" the following biological endpoints are addressed: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and hemolysis.

Sterilization and shelf life

The sterility of the K-Pack Enhance Needle is assured by using a validated sterilization method qualified in accordance with ISO 11135:2014 "Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices" to ensure that not more than one living micro-organism is present in 1 x 10^6 sterilized units of the final product.

The physical validation of the sterilizer is conducted to verify the temperature and humidity in the sterilization load and the pressure in the sterilizer during the whole cycle.

The biological validation is performed in accordance with ISO 11135:2014 Annex B "Conservative determination of lethal rate of the sterilization process – Overkill approach" part B.1.2.a "Half cycle approach". This resulted in a holding time of 120 min for the sterilization cycle to assure a SAL of at least 10^{-6} according to the requirements of ISO 11135:2014.

The allowable limits for residual EO and ECH are calculated taking into consideration the categorization of the K-Pack Enhance Needle as a device with limited exposure for which the cumulative single, multiple or repeated use or contact is up to 24 hours based on the approached described in ISO 10993-7:2008 second edition.

The limits for the bacterial endotoxin testing LAL (Limulus Amebocyte Lysate) performed as part of the release criteria are aligned with the requirements described in USP <85> and <161>.

Accelerated aging is performed based on ASTM F1980: "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices" to support 5 years shelf life.

9. Clinical Test (*807.92(b)(2)*)

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

10. Conclusion (*807.92(b)(3)*)

In summary, the K-Pack Enhance Needle, manufactured by Terumo Europe, being the subject of this 510(k), is substantially equivalent to its predicate device:

- K-Pack II Needle 27G x 1/2” Thin Wall (K110850) manufactured by Terumo Europe N.V.

There are no differences in intended use and indications for use between the subject device and the predicate device.

The differences in the technological characteristics (i.e. device materials and device design) do not raise any new or different issues of safety or effectiveness when compared to the predicate device. The K-Pack Enhance Needle is as safe and effective, and performs as well as the legally marketed predicate device.