May 29, 2025

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

Re: K243309
Trade/Device Name: 27G x 1/2" TW K-Pack Surshield Needle (KN-S2713RBT)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 4, 2025
Received: May 2, 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)*
K243309

Device Name
27G x 1/2" TW K-Pack Surshield Needle (KN-S2713RBT)

Indications for Use *(Describe)*
The 27G x 1/2" TW K-Pack Surshield Needle is a hypodermic needle with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.

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

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:	September 2024

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

Proprietary Name:	27G x ½" TW K-Pack Surshield Needle
Common Name:	Hypodermic Needle
Classification Name:	Hypodermic Single Lumen Needle
Classification Panel:	General Hospital
Regulation:	21CFR, Section §880.5570
Product Code:	FMI
Classification:	Class II

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

The legally marketed device(s) to which substantial equivalence is claimed:

- 27G x ½" K-Pack Surshield Needle (K111797) manufactured by Terumo Europe N.V.

4. Reason for 510(k) Submission

This premarket notification [510(k)] is being submitted for the 27G x ½" TW K-Pack Surshield Needle to provide supporting information that the proposed device is safe and effective and substantially equivalent to the following devices:

- 27G x ½" K-Pack Surshield Needle (K111797) manufactured by Terumo Europe N.V.

The change proposed in this submission is the 27G x ½" TW K-Pack Surshield Needle which has an increased cannula's inner diameter and therefore different cannula wall thickness (thin wall vs regular wall) compared to the 27G x ½" K-Pack Surshield Needle (K111797).

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

Principle of Operation Technology

The 27G x ½" TW K-Pack Surshield Needle is operated manually or by manual process.

Design/Construction

The 27G x ½" TW K-Pack Surshield Needle is a hypodermic single lumen needle, for single use consisting of a stainless-steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. Furthermore, the needle has a passive sharps protection feature that covers the cannula immediately and permanently after use to prevent the risk of accidental needle stick injuries. The needle is non-toxic, non-pyrogenic and sterilized by ethylene oxide. Its operation is manual. The 27G x ½" TW K-Pack Surshield Needle is packed in a hard plastic container (cap and case) made of polypropylene and sealed with a label and sterilized by ethylene oxide.

Specifications

The following table shows the product codes, needle gauge and needle length.

Table 1 - Product Specifications

Product Code	Needle Gauge	Needle Length	Needle bevel	Cannula wall
KN-S2713RBT	27G (0.4 mm)	½" (12 mm)	Regular bevel	Thin Wall (TW)

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

The 27G x ½" TW K-Pack Surshield Needle is a hypodermic needle with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.

Note: Indications for use of the subject device are the same as for the following predicate device:

- 27G x ½" K-Pack Surshield Needle (K111797) manufactured by Terumo Europe N.V.

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

The 27G x ½" TW K-Pack Surshield Needle, the subject of this 510(k), is substantially equivalent to the following predicate devices:

- 27G x ½" K-Pack Surshield Needle (K111797) manufactured by Terumo Europe N.V.

The similarities and differences are summarized below.

Table 2 - Intended Use/Indications for Use

Characteristics	Subject Device: 27G x ½" TW K-Pack Surshield Needle	Predicate device: 27G x ½" K-Pack Surshield Needle (K111797)	Comments
Indications for Use	The 27G x ½" TW K-Pack Surshield Needle is a hypodermic needle with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.	The 27G x ½" K-Pack Surshield Needle is a hypodermic needle with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.	Same indications for use
Intended Use	The K-Pack Surshield Needle is for general application – for treatment (subcutaneous or intramuscular injection).	The K-Pack Surshield Needle is for general application – for treatment (subcutaneous or intramuscular injection).	Same intended use
Prescription or OTC (over the counter)	Prescription	Prescription	Same

Table 3 - Technological characteristics

Characteristics	Subject Device: 27G x ½" TW K-Pack Surshield Needle	Predicate device: 27G x ½" K-Pack Surshield Needle (111797)	Comments
Manufacturer	Terumo Europe N.V.	Terumo Europe N.V.	Same manufacturer
Materials	Cannula – Stainless Steel Hub – Polypropylene/ Colour Masterbatch Basecover – Polypropylene/ Colour Masterbatch Sheath – MehtylMethacrylate Acrylonitrile Butadiene Styrene (MABS) Ring – Polyoxymethylene (POM)/ Colour Masterbatch/ Slipping Agent Stopper – Polycarbonate Guide – Polypropylene Spring – Stainless Steel Glue – Acrylic Glue (UV cured) Lubricant – Silicone oil Case – Polypropylene Cap – Polypropylene Label – Self-Adhesive Paper Label	Cannula – Stainless Steel Hub – Polypropylene/ Colour Masterbatch Basecover – Polypropylene/ Colour Masterbatch Sheath – MehtylMethacrylate Acrylonitrile Butadiene Styrene (MABS) Ring – Polyoxymethylene (POM)/ Colour Masterbatch/ Slipping Agent Stopper – Polycarbonate Guide – Polypropylene Spring – Stainless Steel Glue – Acrylic Glue (UV cured) Lubricant – Silicone oil Case – Polypropylene Cap - Polypropylene Label – Self-Adhesive Paper Label	Same materials

Characteristics	Subject Device: 27G x ½" TW K-Pack Surshield Needle	Predicate device: 27G x ½" K-Pack Surshield Needle (111797)	Comments
Design/ Constructions	The 27G x ½" TW K-Pack Surshield Needle is a Hypodermic single lumen needle, for single use consisting of a stainless-steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. Furthermore, the needle has a passive sharps protection feature that covers the cannula immediately and permanently after use. The 27G x ½" TW K-Pack Surshield Needle is packed in a hard plastic container (cap and case) made of polypropylene and sealed with a label.	The 27G x ½" K-Pack Surshield Needle is a Hypodermic single lumen needle, for single use consisting of a stainless-steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. Furthermore, the needle has a passive sharps protection feature that covers the cannula immediately and permanently after use. The 27G x ½" K-Pack Surshield Needle is packed in a hard plastic container (cap and case) made of polypropylene and sealed with a label.	Same design/construction Both needles are designed in accordance with ISO 7864 and ISO 80369-7.
Specifications	27G x ½" (0.4 x 12 mm) Thin Wall Regular Bevel Outside diameter Min. 0.40 mm – Max. 0.42 mm Inner diameter Min. 0.241 mm – Max. 0.281 mm	27G x ½" (0.4 x 12 mm) Regular Wall Regular Bevel Outside diameter Min. 0.40 mm – Max. 0.42 mm Inner diameter Min. 0.20 mm – Max. 0.24 mm	Increased cannula's inner diameter and therefore different cannula wall thickness (thin wall vs regular wall) Cannula specifications are in accordance with ISO 9626
Principle of Operation	Manual	Manual	Same operation principle

Unit packaging	Hard plastic container consisting of cap and case	Hard plastic container consisting of cap and case	Same packaging system validated in accordance with ISO 11607-1 and ISO 11607-2

Characteristics	**Subject Device: 27G x ½" TW K-Pack Surshield Needle**	**Predicate device: 27G x ½" K-Pack Surshield Needle (111797)**	**Comments**
Sterilization	EO to SAL 10^{-6}	EO to SAL 10^{-6}	Same sterilization validation process in accordance with ISO 11135 Bacterial endotoxin limits and EO residual limits (ISO 10993-7) are the same
Shelf life	5 years	5 years	Same shelf life

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

There are no differences in the Intended Use and Indications for Use and the differences in the technological characteristics of the subject device to the predicate device are supported by the below performance verification:

- Performance verification is evaluated according to the following standards: ISO 7864 and ISO 9626. The same standards were utilized for the predicate device 27G x ½" K-Pack II Needle (K111797) to demonstrate performance.

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

Performance

The design of the 27G x ½" TW K-Pack Surshield Needle is 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 "Stainless steel needle tubing for the manufacturing of medical devices"

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

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 27G x ½" TW K-Pack Surshield Needles are categorized following the definitions in EN ISO 10993-1:2020 as external communicating devices that can contact tissue, or that can indirectly contact the blood path up to 24 hours (limited exposure).

Based on this classification and 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 applicable biological endpoints are: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, bacterial endotoxins and haemocompatibility (material-induced haemolysis).

Sterilization and shelf life

The sterility of the 27G x ½" TW K-Pack Surshield Needle is assured by using a validated sterilization method qualified in accordance with EN 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".

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 EN ISO 11135:2014 Annex B "Conservative determination of lethal rate of the sterilization process – Overkill approach" part B.1.2.b "Cycle calculations". 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 EN ISO 11135:2014.

The products can therefore be labelled sterile in accordance with EN 556-1:2001/AC1:2006 "Sterilization of medical devices - Requirements for medical devices to be labelled STERILE - Part 1: Requirements for terminally sterilized medical devices".

The levels of residual EO and ECH are defined in accordance with ISO 10993-7 'Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals".

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

The shelf life of the 27G x ½" TW K-Pack Surshield Needle is 5 years.

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

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

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

In summary, the 27G x ½" TW K-Pack Surshield Needle, manufactured by Terumo Europe N.V., being the subject of this 510(k), is substantially equivalent to its predicate device:

- 27G x ½" K-Pack Surshield Needle (K111797) manufactured by Terumo Europe N.V.

There are no differences in the Intended Use and Indications for Use and the differences in the technological characteristics, do not raise any new or different questions of safety or effectiveness when compared to the predicate device. The 27G x ½" TW K-Pack Surshield Needle is as safe and effective, and performs as well as the legally marketed predicate device.