July 8, 2025

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

Re: K251447
Trade/Device Name: K-Pack Embrace™ Active Safety Needle (KNAS-2516RB, KNAS-2525RB)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 9, 2025
Received: May 9, 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)*
K251447

Device Name
K-Pack Embrace™ Active Safety Needle (KNAS-2516RB, KNAS-2525RB)

Indications for Use *(Describe)*
Intended Purpose: The K-Pack Embrace™ Active Safety Needle, being a hypodermic needle with safety shield, is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The safety shield shall be manually locked (activated), after use, to cover the needle to minimize the risk of accidental needle stick.

Indications: The K-Pack Embrace™ Active Safety Needle is for general application – for treatment (injection of fluids) or diagnosis (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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

514475 510(k) Summary

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:	June 27, 2025

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

Proprietary Name:	K-Pack Embrace™ Active Safety Needle (KNAS-2516RB, KNAS-2525RB)
Common Name:	Hypodermic needle with safety shield
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(s) to which substantial equivalence is claimed:

- SURGUARD3 SAFETY HYPODERMIC NEEDLE (K212095) manufactured by Terumo Europe N.V.

4. Reason for 510(k) Submission

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

- SurGuard 3 Safety Hypodermic Needle 25G x 5/8” Thin Wall (K212095) manufactured by Terumo Europe N.V.
- SurGuard 3 Safety Hypodermic Needle 19G x 1” Thin Wall (K212095) manufactured by Terumo Europe N.V.

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

Principle of Operation Technology

The K-Pack Embrace™ Active Safety Needle is operated manually or by manual process.

Design/Construction

The K-Pack Embrace™ Active Safety Needle is a hypodermic single lumen needle, for single use consisting of stainless steel cannula that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polycarbonate designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. The K-Pack Embrace™ Active Safety Needle is compatible for use with standard luer slip and luer lock syringes. The K-Pack Embrace™ Active Safety Needle is packed in a hard plastic container (cap and case) made of polypropylene and sealed with a label.

This device features a hinged safety shield, made of polycarbonate, attached to the needle hub. The safety feature is activated when the safety shield is manually pressed over the needle immediately after use and prior to disposal to minimize the risk of accidental needle stick injuries. The safety shield is activated with a one-handed operation, using the finger, thumb, or surface activation.

The K-Pack Embrace™ Active Safety Needle is sterilized by ethylene oxide.

Materials

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

Table 1 - List of Components and their Raw Materials

Component/Part	Material
Cannula	Stainless Steel
Hub	Polycarbonate + Color Masterbatch
Protector	Polypropylene
Shield	Polycarbonate
Adhesive	Acrylic Adhesive (UV cured glue)
Lubricant	Silicone oil
	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
KNAS-2525RB	25G – 0.5 mm	1"– 25 mm	Long (regular) bevel	Thin
KNAS-2516RB	25G – 0.5 mm	5/8"– 16 mm	Long (regular) bevel	Thin

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

Intended Purpose: The K-Pack Embrace™ Active Safety Needle, being a hypodermic needle with safety shield, is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The safety shield shall be manually locked (activated), after use, to cover the needle to minimize the risk of accidental needle stick.

Indications: The K-Pack Embrace™ Active Safety Needle is for general application – for treatment (injection of fluids) or diagnosis (withdrawal of fluids).

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

The K-Pack Embrace™ Active Safety Needle (KNAS), manufactured by Terumo Europe, being the subject of this 510(k), is substantially equivalent to its predicate devices:

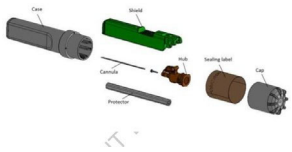
- SurGuard 3 Safety Hypodermic Needle 25G x 5/8" Thin Wall (K212095) manufactured by Terumo Europe N.V.
- SurGuard 3 Safety Hypodermic Needle 19G x 1" Thin Wall (K212095) manufactured by Terumo Europe N.V.

The similarities and differences are summarized below.

Table 3 - Indications for Use

Characteristics	Subject Device: K-Pack Embrace Active Safety Needle	Predicate device: SURGUARD3 SAFETY HYPODERMIC NEEDLE (K212095)	Comments
Indications for Use	The K-Pack Embrace Active Safety Needle, being a hypodermic needle with safety shield, is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The safety shield shall be manually locked (activated), after use, to cover the needle to minimize the risk of accidental needle stick.	The SurGuard3 Safety Hypodermic Needle is intended for use in the aspiration and injection of fluids for medical purposes. The Safety Hypodermic Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield shall be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	Same indication for use. 'Aspiration of fluids' is the same as 'withdraw fluids'. The subject device is also used for medical purposes and is also compatible for use with standard luer slip and luer lock syringes although not mentioned.
Prescription or OTC (over the counter)	Prescription	Prescription	Identical

Table 4 - Technological characteristics

Characteristics	Subject Device: K-Pack Embrace Active Safety Needle	Predicate device: SURGUARD3 SAFETY HYPODERMIC NEEDLE (K212095)	Comments
Manufacturer	Terumo Europe N.V.	Terumo Europe N.V.	Identical
Materials	Cannula – Stainless Steel Hub – Polycarbonate/ Masterbatch Safety Shield (sheath) – Polycarbonate Protector – Polypropylene, masterbatch Adhesive – Acrylic Glue Lubricant – Silicone oil (Polydimethylsiloxane)	Cannula – Stainless Steel Hub - Polypropylene/ Masterbatch Collar - Polypropylene Sheath (Safety Shield) - Polypropylene Protector – Polypropylene Adhesive – Epoxy Glue Lubricant – Silicone oil (Polydimethylsiloxane)	Different The collar of the predicate device is part of the hub of the subject device (see design below). Exact same material used for the cannula. See substantial equivalence discussion for all other materials.
Design	The device consists of a hypodermic needle with a hinged safety shield attached to the connector hub. (case, cap and sealing label is part of the unit packaging described below) 	The device consists of a hypodermic needle with a hinged safety shield attached to the connector hub. 	Different The design of the ssubjectdevice follows the same design requirements as described in ISO 7864, ISO 9626 and ISO 80369-7.

Characteristics	Subject Device: K-Pack Embrace Active Safety Needle	Predicate device: SURGUARD3 SAFETY HYPODERMIC NEEDLE (K212095)	Comments
Specifications	-**KNAS-2516RB:** 25G x 5/8" (0.5 x 16 mm), Thin Wall, Long (Regular) Bevel -**KNAS-2525RB**: 25G x 1" (0.5 x 25 mm), Thin Wall, Long (Regular) Bevel	-**SG3-2516RB**: 25G x 5/8" (0.5 x 16 mm), Thin Wall, Long (Regular) Bevel -**SG3-1925RB**: 19G x 1" (1.1 x 25 mm), Thin Wall, Long (Regular) Bevel	Different All needles specifications in accordance with ISO 7864 and the predicate device covers both the gauge and the needle length size of the subject device. See Substantial Equivalence discussion.
Principle of Operation	Manual	Manual	Same operation principle. Manual use in accordance with ISO 7864. Connection with syringes in accordance with ISO 80369-7.
Safety shield	Manual activation	Manual activation	Same activation principle of the safety shield in accordance with ISO 23908.
Unit packaging	Hard pack consisting of cap and case out of polypropylene and sealed with a label (see design/construction above)	Hard blister pack consisting of blister lid coated paper and thermoformable plastic film	Different Packaging evaluation in accordance with ISO 11607-1 and ISO 11607-2.

Sterilization	EO to SAL 10^{-6}	EO to SAL 10^{-6}	Identical. Sterilization validation in accordance with ISO 11135. Device can therefore be labelled sterile in accordance with EN 556-1. Residual EO and ECH in accordance with ISO 10993-7.
Shelf life	5 years	5 years	Identical

Substantial Equivalence Discussion

The subject device is substantially equivalent to the predicate device when evaluating indication for use and technological characteristics given that:

The technological characteristics of the subject device are substantially equivalent to the predicate device with only minor differences in device materials (hub, adhesive, safety shield, lubricant, protector), design and unit packaging.

- Subject device has a different cannula design. The subject device has a 25G cannula model with a 1 inch (25mm) cannula length (KNAS-2525RB) compared to the predicate's 25G cannula with a 5/8 inch (16mm) cannula length (SG3-2516RB) and the predicate 19G cannula with a 1 inch (25mm) cannula length (SG3-1925RB). Design verification has been evaluated according to ISO 7864:2016, ISO 9626:2016 and ISO 80369-7:2017. 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.
- Subject device has a different packaging design. Packaging verification and validation has been evaluated according to ISO 11607-1: 2019 and ISO 11607-2: 2019 for both the subject device as the predicate device. 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.
- Subject device has different materials of construction in its hub, adhesive, safety shield, lubricant, protector. 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.

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

Performance

The design of the K-Pack Embrace Safety Needle has been verified 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 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

Agency Guidance "Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff"

Biocompatibility

The K-Pack Embrace Active Safety Needles are categorized following the definitions in ISO 10993-1 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 Embrace Active Safety 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 Embrace Active Safety 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.

Chemical extraction on the finished product has been performed in accordance with ISO 10993-18. Toxicological assessment was made according ISO 10993-17 for the elemental impurities above the AET (Analytical Evaluation Threshold) and concluded that no toxicological risk were posed.

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 haemocompatibility.

Sterilization and shelf life

The sterility of the K-Pack Embrace Active Safety 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 no 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.b “Cycle calculations 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 products can therefore be labelled sterile in accordance with EN 556-1:2024 *“Sterilization of medical devices - Requirements for medical devices to be labelled STERILE - Part 1: Requirements for terminally sterilized medical devices”.*

The allowable limits for residual EO and ECH are calculated taking into consideration the categorization of the K-Pack Embrace Active Safety 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/ A1:2019.

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.

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

- SURGUARD3 SAFETY HYPODERMIC NEEDLE (K212095) manufactured by Terumo Europe N.V.

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

The differences in the technological characteristics (device materials, device design and unit packaging), do not raise any new or different questions of safety or effectiveness when compared to the predicate device. The subject device is substantially equivalent to the predicate device.