August 22, 2022

Terumo Europe N.V.
M.J. Aerts
VP Regulatory & Vigilance
Interleuvenlaan 40
Leuven, 3001
Belgium

Re: K212095
Trade/Device Name: SurGuard3 Safety Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 27, 2022
Received: June 27, 2022

Dear M.J. Aerts:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

CAPT Alan M. Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212095

Device Name
SurGuard®3 SAFETY HYPODERMIC NEEDLE

Indications for Use *(Describe)*
The TERUMO SurGuard®3 SAFETY HYPODERMIC NEEDLE is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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 sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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
K212095

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

Prepared for:	TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM
Prepared by/Contact person:	Mrs. M.J. Aerts – VP Regulatory & Vigilance Tel. (+32) 16 38 13 53 Fax (+32) 16 40 02 49
Date prepared:	August 19, 2022

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

Proprietary Name:	SurGuard®3 Safety Hypodermic Needle
Common Name:	Hypodermic needle with safety sheath or needle with needle protection device
Classification Name:	Hypodermic Single Lumen Needle
Classification Panel:	General Hospital
Regulation:	21 CFR §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:

-Primary Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K113422) manufactured by Terumo (Philippines) Corporation, 21 CFR §880.5570, Product Code: FMI, MEG

-Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K122249) manufactured by Terumo (Philippines) Corporation, 21 CFR §880.5570, Product Code: FMI, MEG

4. Reason for 510(k) Submission

This premarket notification [510(k)] is being submitted for the SurGuard®3 Safety Hypodermic Needle to provide supporting information that the proposed device is safe and effective and substantially equivalent to the following devices:

Primary Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K113422) manufactured by Terumo (Philippines) Corporation.

Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K122249) manufactured by Terumo (Philippines) Corporation

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

Principle of Operation Technology

The SurGuard®3 Safety Hypodermic Needle is operated manually or by manual process.

Design/Construction

The SurGuard®3 Safety Hypodermic 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 polypropylene designed to be connected with a male luer connector (nozzle) of a hypodermic syringe. The SurGuard®3 Safety Hypodermic Needle is compatible for use with standard luer slip and luer lock syringes. The needles are packed in a hard blister made of thermoformable blister film and blister lidding paper. This device features a hinged safety sheath attached to the needle hub. The safety sheath contains two locking mechanisms, the tooth-cannula and sheath-collar which are simultaneously activated when manually pressed over the needle immediately after use and just prior to disposal to minimize the risk of accidental needlestick. The safety sheath is activated with a one-handed operation, using the finger, thumb, or surface activation.
The SurGuard®3 Safety Hypodermic Needle will be individually packaged and sterilized by ethylene oxide.

Specifications

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

Table 5.2 Product Specifications

PRODUCT CODE	NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL	CANNULA WALL
SG3-1925RB	19 G (1.1 mm)	1" (25 mm)	Long bevel	Thin wall
SG3-1938RB	19 G (1.1 mm)	1 ½" (38 mm)	Long bevel	Thin wall
SG3-2138RB	21 G (0.8 mm)	1 ½" (38 mm)	Long bevel	Thin wall
SG3-2516RB	25 G (0.5 mm)	5/8" (16 mm)	Long bevel	Thin wall

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

The TERUMO SurGuard®3 SAFETY HYPODERMIC NEEDLE is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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 sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Note: The indications for use are identical to the following predicate devices:

- Primary Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K113422) manufactured by Terumo (Philippines) Corporation.
- Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K122249) manufactured by Terumo (Philippines) Corporation

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

SurGuard® 3 SAFETY HYPODERMIC NEEDLE, the subject of this 510(k), is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials, and performance to the following predicate devices:

- Primary Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K113422) manufactured by Terumo (Philippines) Corporation.
- Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K122249) manufactured by Terumo (Philippines) Corporation

The similarities and differences are summarized in table 5.3.

Table 5.3 Device Comparison Table

Characteristics	Subject Device: SurGuard®3 Safety Hypodermic Needle (Terumo Europe, Belgium) (K212095)	Primary Predicate device: Terumo SurGuard®3 Safety Hypodermic Needle (Terumo (Philippines) Corporation (Philippines)) (K113422)	Predicate device: Terumo SurGuard®3 Safety Hypodermic Needle (Terumo (Philippines) Corporation (Philippines)) (K122249)	Comments
Manufacturer	Terumo Europe N.V.	Terumo (Philippines) Corporation	Terumo (Philippines) Corporation	
Indications for Use*	The TERUMO SurGuard® 3 SAFETY HYPODERMIC NEEDLE is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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 sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	The TERUMO SurGuard® 3 SAFETY HYPODERMIC NEEDLE is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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 sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	The TERUMO SurGuard® 3 SAFETY HYPODERMIC NEEDLE is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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 sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	Unchanged
Materials	Cannula – Stainless Steel Hub - Polypropylene/Masterbatch Protector – Polypropylene Adhesive – Epoxy Glue Collar – Polypropylene Sheath – Polypropylene Lubricant - Polydimethylsiloxane	Cannula – Stainless Steel Hub - Polypropylene/Masterbatch Protector – Polypropylene Adhesive – Epoxy Glue Collar – Polypropylene Sheath – Polypropylene Lubricant - Polydimethylsiloxane	Cannula – Stainless Steel Hub -Polypropylene/Masterbatch Protector – Polypropylene Adhesive – Epoxy Glue Collar – Polypropylene Sheath – Polypropylene Lubricant - Polydimethylsiloxane	Unchanged
Design/ Constructions	The device consists of a hypodermic needle with a hinged safety sheath attached to the connector hub.	The device consists of a hypodermic needle with a hinged safety sheath attached to the connector hub.	The device consists of a hypodermic needle with a hinged safety sheath attached to the connector hub.	Unchanged

Characteristics	Subject Device: SurGuard®3 Safety Hypodermic Needle (Terumo Europe, Belgium) (K212095)	Primary Predicate device: Terumo SurGuard®3 Safety Hypodermic Needle (Terumo (Philippines) Corporation (Philippines)) (K113422)	Predicate device: Terumo SurGuard®3 Safety Hypodermic Needle (Terumo (Philippines) Corporation (Philippines)) (K122249)	Comments
Specifications	19G x 1" (1.1 x 25 mm) 19G x 1 ½" (1.1 x 38 mm) 21G x 1 ½" (0.8 x 38 mm) 25G x 5/8" (0.5 x 16 mm)	19G x 1" (1.1 x 25 mm) 19G x 1 ½" (1.1 x 38 mm) 21G x 1 ½" (0.8 x 38 mm)	25G x 5/8" (0.5 x 16 mm)	Unchanged
Principle of Operation	Manual	Manual	Manual	Unchanged
Unit packaging	Hard blister pack consisting of blister lid coated paper and thermoformable plastic film	Soft blister pack consisting of blister lid coated paper and thermoformable plastic film	Soft blister pack consisting of blister lid coated paper and thermoformable plastic film	Refer to Substantial Equivalence Discussion
Sterilization	EO to SAL 10^{-6}	E-beam radiation to SAL 10^{-6}	E-beam radiation to SAL 10^{-6}	Refer to Substantial Equivalence Discussion
Shelf life	5 years	5 years	5 years	Unchanged

Substantial Equivalence Discussion

SurGuard®3 Safety Hypodermic Needle is the same needle as the SurGuard®3 Safety Hypodermic Needles cleared in K113422 and K122249 given that:

- It has the same intended use and indications for use as the predicate devices
- It uses the same principles of operation
- It incorporates the same basic design
- It is manufactured from the same materials
- It is sterilized in accordance with validated methods
- It is sterilized to a Sterility Assurance Level (SAL) of 10^{-6}
- It has the same shelf life

The specifications of the subject device are the same of the ones already covered in K113422 and K122249.Terumo Europe buys SurGuard®3 Safety Hypodermic Needle in bulk from Terumo (Philippines) Corporation and then packs the product in a hard blister pack. Therefore, the difference is that the needle subject to this 510(k) file is packed in a hard blister pack consisting of blister lid coated paper and thermoformable plastic film instead of a soft blister pack, which is the case for the predicate devices. There is also a difference in the sterilization method (EO sterilization compared to E-beam sterilization) but the same sterility assurance level is achieved.

Based on the above explanation and supported by performance testing, it can be concluded that differences between the subject and the predicate devices do not impact safety and effectiveness.

Table 5.4 Product specifications

	Subject Device:	**Primary Predicate (K113422)**	**Predicate device (K122249)**
Product Specifications	19G x 1” (1.1 x 25 mm) 19G x 1 ½” (1.1 x 38 mm) 21G x 1 ½” (0.8 x 38 mm) 25G x 5/8” (0.5 x 16 mm)	19G x 1” (1.1 x 25 mm) 19G x 1 ½” (1.1 x 38 mm) 21G x 1 ½” (0.8 x 38 mm)	25G x 5/8” (0.5 x 16 mm)

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

Performance

The design of the SurGuard®3 Safety Hypodermic 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: 2017 “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 23908:2013 Sharps injury protection – Requirements and test methods – Sharps protection features for single-used hypodermic needles, catheters, introducers for catheters and needles used for blood sampling

USP <788> Particulate matter

Biocompatibility

The SurGuard®3 Safety Hypodermic Needles are categorized following the definitions in ISO 10993-1:2020 as external communicating devices that can indirectly contact the blood path up to 24 hours (short term exposure). 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, toxicity (acute systemic toxicity, material-induced pyrogenicity, bacterial endotoxins) and haemocompatibility.

Sterilization

The sterility of the SurGuard®3 Safety Hypodermic Needles 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”.

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 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”.

In accordance with ISO 10993-7:2008/AC:2009: “Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals” the residual ethylene oxide level after aeration does not exceed 4 mg/device/day and the ethylene chlorohydrin level does not exceed 9 mg/device/day.

Accelerated aging is performed based on ASTM F1980: “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”.

Simulated shipping is performed per ASTM D4169-16: “Standard Practice for Performance Testing of Shipping Containers and Systems”.

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 SurGuard®3 Safety Hypodermic Needle, manufactured by Terumo Europe, being the subject of this 510(k), is substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following devices:

- Primary Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K113422) manufactured by Terumo (Philippines) Corporation.
- Predicate Device: Terumo SurGuard®3 Safety Hypodermic Needle (K122249) manufactured by Terumo (Philippines) Corporation

Differences between the devices do not raise any new issues of safety or effectiveness.