



October 18, 2023

Terumo Europe N.V.
Liesbeth Decoster
Regulatory Affairs Manager
Interleuvenlaan 40
Leuven, 3012
Belgium

Re: K230951

Trade/Device Name: Terumo Injection Filter Needle (NF-3013RBKE05M)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: QYM
Dated: September 15, 2023
Received: September 15, 2023

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.

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, **Juliane C. Lessard -S**

Juliane C. Lessard, Ph.D.

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)
K230951

Device Name
Terumo Injection Filter Needle (NF-3013RBKE05M)

Indications for Use (Describe)

The Terumo Injection Filter Needle is intended to inject fluids.

The Terumo Injection Filter Needle is indicated for general application - for treatment - injection of fluids into parts of the body below the surface of the skin and into the vitreous.

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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K230951 510(k) SUMMARY

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

Prepared for: TERUMO EUROPE N.V.
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Prepared by/Contact Person: Mrs. L. Decoster – Regulatory Affairs Manager
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49

Date prepared: October 2023

Note: Class III Summary & Certification is not applicable for the submission of a Class II device



510(k) SUMMARY

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

Prepared for: TERUMO EUROPE N.V.
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3001 Leuven,
BELGIUM

Prepared by/Contact person: Mrs. L. Decoster – Regulatory Affairs Manager
Tel. (+32) 16 38 13 02
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Date prepared: March 2023

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

Proprietary Name: Terumo Injection Filter Needle
Common Name: Injection Filter Needle
Classification Name: Hypodermic Single Lumen Needle
Classification Panel: General Hospital
Regulation: 21CFR, Section §880.5570
Product Code: QYM (Ophthalmic Needle)
Classification: Class II

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

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

- K-Pack II Needle 27G x 1/2" Extra Thin Wall, 27G x 1/2" Ultra Thin Wall, 30G x 1/2" Extra Thin Wall and 30G x 1/2" Ultra Thin Wall (K192057) manufactured by Terumo Europe N.V.

4. Reason for 510(k) Submission

This premarket notification [510(k)] is being submitted for the Terumo Injection Filter Needle to provide supporting information that the proposed device is safe and effective and substantially equivalent to the following devices:

- K-Pack II Needle 27G x 1/2" Extra Thin Wall, 27G x 1/2" Ultra Thin Wall, 30G x 1/2" Extra Thin Wall and 30G x 1/2" Ultra Thin Wall (K192057) manufactured by Terumo Europe N.V.

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

Principle of Operation Technology

The Terumo Injection Filter Needle is operated manually or by manual process.

Design/Construction

The Terumo Injection Filter Needle is a sterile injection needle for single use consisting of a stainless steel cannula with nominal outside diameter of 0.3 mm and length of 12 mm that is sharpened at one end and at the other end joined to a female luer connector (hub)



made of polymethyl methacrylate designed to be connected with a male luer connector (nozzle) of a syringe. The integrated 5µ filter in the hub is intended to prevent particles from being injected. The needle is non-toxic, nonpyrogenic and sterilized by ethylene oxide. Its operation is manual. The Terumo Injection Filter Needle has a needle protector and is individually packed in a soft blister made of paper and film 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
NF-3013RBKE05M	30 G (0.3 mm)	1/2" (12 mm)	Regular bevel	Extra-thin

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

The Terumo Injection Filter Needle is intended to inject fluids. The Terumo Injection Filter Needle is indicated for general application - for treatment - injection of fluids into parts of the body below the surface of the skin and into the vitreous.

Note: The Terumo Injection Filter Needle has equivalent intended use as the following predicate devices, being the subject device additionally indicated for injection of fluids into the vitreous:

- K-Pack II Needle 27G x 1/2" Extra Thin Wall, 27G x 1/2" Ultra Thin Wall, 30G x 1/2" Extra Thin Wall and 30G x 1/2" Ultra Thin Wall (K192057) manufactured by Terumo Europe N.V.

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

The Terumo Injection Filter Needle, the subject of this 510(k), is substantially equivalent to the following predicate devices:

- K-Pack II Needle 27G x 1/2" Extra Thin Wall, 27G x 1/2" Ultra Thin Wall, 30G x 1/2" Extra Thin Wall and 30G x 1/2" Ultra Thin Wall (K192057) manufactured by Terumo Europe N.V.

The similarities and differences are summarized below.



Table 2 - Intended Use/Indications for Use

Characteristics	Subject Device: Terumo Injection Filter Needle 30G x 1/2" ETW 5µm filter	Predicate device: K-Pack II Needle 27G x 1/2" ETW, 27G x 1/2" UTW, 30G x 1/2" ETW and 30G x 1/2" Ultra Thin Wall (K192057)	Comments
Intended Use	The Terumo Injection Filter Needle is a sterile medical device for single use intended to inject fluids.	The K-Pack II Needles being Hypodermic Single Lumen Needles are sterile medical devices for single use intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	SE
Indications for Use	For general application - for treatment - injection of fluids into parts of the body below the surface of the skin and the vitreous.	Indications for Use: No specific indications for use identified	SE
Prescription or OTC (over the counter)	Prescription	Prescription	Same

Table 3 - Technological characteristics

Characteristics	Subject Device: Terumo Injection Filter Needle 30G x 1/2" ETW 5µm filter	Predicate device: K-Pack II Needle 27G x 1/2" ETW, 27G x 1/2" UTW, 30G x 1/2" ETW, 30G x 1/2" UTW (K192057)	Comments
Manufacturer	Terumo Europe N.V.	Terumo Europe N.V.	Same manufacturer
Materials	Cannula – Stainless Steel Hub – PMMA/ Masterbatch Adhesive – Acrylic Glue Lubricant – Silicone (Polydimethylsiloxane) Filter component – 5µm mesh woven polyamide filter	Cannula – Stainless Steel Hub - Polypropylene/ Masterbatch Adhesive – Epoxy Glue Lubricant – Silicone (Polydimethylsiloxane)	SE 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/ Constructions	Same as predicate but with the added feature of a filter welded in the hub	The device consists of a cannula attached to a hub.	SE The subject device additionally has a filter welded in the hub with pore size of 5 µm which its function is supported by filter efficiency testing.
Specifications	30G x ½" Extra Thin Wall Regular Bevel Filter Pore Size 5 µm	30G x ½" Extra Thin Wall Regular Bevel	Same needles specifications in accordance with ISO 7864. The subject device additionally has a filter welded in the hub with pore size of 5 µm which its function is supported by filter efficiency testing.
Principle of Operation	Manual.	Manual	Same operation principle. Manual use in accordance with ISO 7864.



Characteristics	Subject Device: Terumo Injection Filter Needle 30G x 1/2" ETW 5µm filter	Predicate device: K-Pack II Needle 27G x 1/2" ETW, 27G x 1/2" UTW, 30G x 1/2" ETW, 30G x 1/2" UTW (K192057)	Comments
			Connection with syringes in accordance with ISO 80369-7.
Unit packaging	Blister pack consisting of printed paper and film.	Hard pack consisting of cap and case.	SE Packaging evaluation in accordance with ISO 11607-1.
Sterilization	EO to SAL 10 ⁻⁶	EO to SAL 10 ⁻⁶	SE Same sterilization validation process in accordance with ISO 11135. Bacterial endotoxin limits and EO residual limits (ISO 10993-7) are set taking into consideration special devices (ocular).
Shelf life	5 years	5 years	Same shelf life.



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

The subject device is substantially equivalent (SE) to the predicate device when evaluating intended use and indications for use and technological characteristics given that:

- The Terumo Injection Filter Needle is SE to the predicate device with respect to intended use except that the subject device is only intended for injection of fluids not for withdrawal of fluids (from parts of the body below the surface of the skin) due to presence of the filter. The intended use of the Terumo Injection Filter Needle is additionally supported by the necessary information provided within the product labeling and IFU.
- The subject device, being also a prescription use device for the general purpose of injection of fluids into parts of the body below the surface of the skin (hypodermic use) the same as the predicate, is additionally indicated for injection of fluids into the vitreous. This additional intravitreal use is supported by different performance and biocompatibility data (see non-clinical test section) and by the necessary information provided within the product labeling and IFU.
- 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, ISO 9626 and ISO 80369-7. The same standards were utilized for the predicate device K-Pack II Needle (K192057) to demonstrate performance.
 - Particulate testing is evaluated according to USP <788> and USP <789>.
 - Filter efficiency is evaluated considering the test methods described in USP <788> and USP <789>.
 - Packaging verification is evaluated according to ISO 11607-1.
 - Biological evaluation is performed in accordance with ISO 10993-1 to demonstrate the subject device is as safe and effective as the legally marketed predicate device, and that any minor differences in technological characteristics do not raise new or different questions of safety and effectiveness as compared to the predicate device.
 - The Terumo Injection Filter Needle is sterilized following a validated sterilization process to guarantee a sterility assurance level (SAL) of 10^6 same as the predicate device. The requirements for special devices described in ISO 10993-7 have been considered to determine the EO residual limits as well as the appropriate endotoxin levels of devices with ophthalmic use.

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

Performance

The design of the Terumo Injection Filter 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 QYM 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 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 <789> Particulate matter in ophthalmic solutions

USP <71> Sterility test

Biocompatibility

The Terumo Injection Filter Needle are categorized following the definitions in EN ISO 10993-1:2020 as external communicating devices that can contact tissue, bone or dentin or that can indirectly contact the blood path up to 24 hours (short term exposure).

The biological evaluation for the Terumo Injection Filter Needle has been performed taking into consideration its the materials of construction and manufacturing process. The raw materials used for the manufacturing of the Terumo Injection Filter 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 EN ISO 10993-18:2020. Toxicological assessment was made according EN ISO 10993-17:2009 for the elemental impurities above the AET 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, irritation including intracutaneous reactivity and ocular and intraocular irritation, acute systemic toxicity, material-mediated pyrogenicity, and haemocompatibility.

Sterilization and shelf life



The sterility of the Terumo Injection Filter 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”.

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/Amd.1:2019: “Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals”, taking into consideration special situations as described in section 4.3.6 from the standard.

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 FDA’S Guidance “Guidance Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices”.

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 Terumo Injection Filter 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” Extra Thin Wall, 27G x 1/2” Ultra Thin Wall, 30G x 1/2” Extra Thin Wall and 30G x 1/2” Ultra Thin Wall (K192057) manufactured by Terumo Europe N.V.

The differences in the intended use/Indications for Use and the technological characteristics, do not raise any new or different issues of safety or effectiveness. The Terumo Injection Filter Needle is as safe and effective, and performs as well as the legally marketed predicate device.