DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 16, 2015

Terumo (Philippines) Corporation
c/o Ms. Phebe Varghese
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K152362
Trade/Device Name: Terumo SurGuard®3 Safety Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 19, 2015
Received: August 21, 2015

Dear Ms. Varghese:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152362

Device Name
Terumo 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

A. SUBMITTER INFORMATION (807.92(a)(1))

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Date prepared: October 14, 2015

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	Terumo 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

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is the current device, K122249 – Terumo SurGuard®3 Safety Hypodermic Needle, manufactured by Terumo (Philippines) Corporation.

D. REFERENCE DEVICE

Biocompatibility data from K121607 – Terumo Hypodermic Needle, manufactured by Terumo (Philippines) Corporation, was levered for information regarding hub colorants.

E. REASON FOR 510(k) SUBMISSION

This premarket notification (Special 510(k)) is being submitted for the Terumo SurGuard®3 Safety Hypodermic Needle, manufactured by Terumo (Philippines) Corporation, for the following modifications to the current device: new needle length (19mm), new gauge sizes (18, 19, 20, and 22) for 13 and 16mm needle lengths, cleared under K122249, and a modified safety sheath design for all new gauge and needle length combinations.

F. DEVICE DESCRIPTION (807.92(a)(4))

Principle of Operation Technology

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

Design/Construction

The Terumo SurGuard®3 Safety Hypodermic Needle [hereinafter referred to as "SurGuard 3 (Short Sheath 2)"] consists of a hypodermic needle with a hinged safety sheath attached to the connector hub which can be attached to either a luer slip or luer lock syringe. 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 possibility of sharps injury. The safety sheath is activated with a one-handed operation, using the finger, thumb, or surface activation.

The safety sheath has a finger guide area consisting of a circular dent (for thumb activation; see Figure A) and ramp (for finger activation; see Figure B) which provides tactile confirmation that the user's finger is in the appropriate position for performing the activation. The ramp has steps to provide strong grasp when activating the sheath. There are two stoppers which is located at the end of the circular dent and ramp which prevent the user's finger from going towards the cannula during activation. Another method of activation is by manually pressing the safety sheath over the needle using a firm surface.

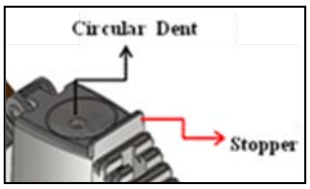

Figure A: Circular dent for thumb activation

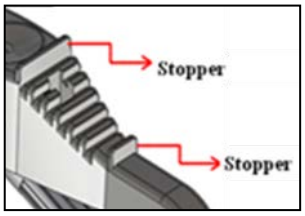

Figure B: Ramp for finger activation

The locking mechanisms are positioned within the center and proximal ends of the sheath. The hinge feature allows the medical practitioner to adjust the sheath to its desired position for use.

The SurGuard 3 (Short Sheath 2) will have two kinds of needle bevel alignment; zero degree bevel alignment and 90 degree bevel alignment. The SurGuard 3 (Short Sheath 2) will be individually packaged and sterilized by electron beam.

Materials

The materials for all SurGuard 3 (Short Sheath 2) sizes are provided in the table below.

Table 5.1: Device Materials

Part Name	Material Name	Manufacturer / Supplier
Cannula*	Stainless Steel	Kaneko Medix / Terumo Corporation
Needle Hub*	Polypropylene	Terumo Corporation
Hub Colorant Base Resin*	Polypropylene + Pigment	Terumo Coporation
Pink*	Quinacridone Red Perylene Red	Terumo Corporation
Cream*	Perylene Red Condenzed Azo Yellow	Terumo Corporation
Yellow*	Perylene Red Condenzed Azo Yellow Titanium Dioxide	Terumo Corporation
Black*	Carbon Black	Terumo Corporation
Needle Protector	Polypropylene	Terumo Corporation
Safety Sheath	Polypropylene	Terumo Corporation
Collar	Polypropylene	Terumo Corporation
Glue	Adhesive (Bond 927-T)	Terumo Corporation
Needle Lubricant*	Reactive Silicone	Terumo Corporation

*Body contacting material

Specifications

The new needle gauge sizes to be added under this 510(k) are: 18G, 19G, 20G, and 22G; additionally, a new needle length of 19mm will be added. This submission also provides new gauge and length combinations for the 13mm and 16mm needle lengths, which were cleared under K122249. Finally, this submission includes a modified design for the short sheath for all new gauge and needle length combinations.

The SurGuard 3 (Short Sheath 2) features a modified short sheath designed to allow activation of the safety sheath with larger gauge sizes of short needle lengths. Because the needle is captured and locked inside the tooth cannula part of the safety sheath, the short sheath internal clearances and tooth thicknesses were modified to

accommodate these kinds of needles.

The following table shows the needle gauge and needle combinations that are new for this submission and those that were cleared under K122249. "X" demonstrates combinations clearance under K122249, and "New" demonstrates combinations proposed for this submission.

Table 5.2: Gauge/Needle Length Combination

Combination		Needle Length				
		3/8" (9mm)	½" (13mm)	5/8" (16mm)	¾" (19mm)	1" (25mm)
Gauge Size	18G		New	New		
	19G		New	New		
	20G		New	New		
	21G					
	22G		New		New	
	23G					X
	25G			X		X
	26G	X	X			
	27G		X			
	30G		X			

G. 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 predicate device, Terumo SurGuard®3 Safety Hypodermic Needle (K122249).

H. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The SurGuard 3 (Short Sheath 2), the subject of this Special 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the Terumo SurGuard®3 Safety Hypodermic Needle, manufactured by Terumo (Philippines) Corporation (K122249).

A comparison of the technological characteristics is summarized in the table below.

Table 5.3: Comparison Between Subject and Predicate Device

Device Characteristic	**Subject Device:** SurGuard 3 (Short Sheath 2)	**Predicate Device:** SurGuard 3 (K122249)
Manufacturer	Terumo (Philippines) Corporation	Same
Intended Use / Indications for Use	The Terumo SurGuard3 Safety Hypodermic Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo SurGuard3 Safety Hypodermic Needle is compatible for use with standard luer slip and luer lock syringes.	Same
Operation Principle	Manual	Same
Design / Construction	Hypodermic needle with integrated safety feature without syringe attached	Same
Materials	• Stainless steel cannula • Polypropylene Hub • Polypropylene Needle Protector • Polypropylene safety feature	Same
Package	• Blister • Shelf box • Shipping box	Same
Specifications	Needle gauges: 18G, 19G, 20G, and 22G Needle length: 13mm, 16mm, and 19mm Safety Sheath: Short sheath 2	Needle gauges: 23G, 25G, 26G, and 27G Needle length: 13mm, 16mm, and 25mm Safety Sheath: Short sheath
Sterilization	E-beam radiation (validated in accordance with ISO 11137-1 to achieve SAL 10^{-6})	Same

The colorant biocompatibility data from the reference device, Terumo Hypodermic Needle (K121607), were levered for the subject device. A comparison of hub colorant

information is summarized in the table below.

Table 5.4: Hub Colorant Information Table

Hub Color	**Subject Device:** SurGuard 3 (Short Sheath 2)	**Reference Device:** Terumo Hypodermic Needle (K121607)
Pink*	Quinacridone Red	Same
	Perylene Red	Same
Cream*	Perylene Red	Same
	Condenzed Azo Yellow	Same
Yellow*	Perylene Red	Same
	Condenzed Azo Yellow	Same
	Titanium Dioxide	Same
Black*	Carbon Black	Same

*Body contacting material

Colorants present on the subject device and K121607 are supplied by Terumo Corporation.

I. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure sterility and functionality of the SurGuard 3 (Short Sheath 2) throughout the labeled shelf life, verify conformity to the applicable parts of ISO standards, and demonstrate substantial equivalence to the predicate device. The following performance tests were performed on the SurGuard 3 (Short Sheath 2):

Table 5.5: Performance Testing per ISO Standards

Test	**Standard**	**Result**
Cleanliness	ISO 7864	N/A
Limits for Acidity or Alkalinity		
Conical Fitting		
Bond Between Hub and Needle Tube		
Adhesive Hold		Meets standard
Exposed cannula length		
Needle Access to the Sharp in Safe Mode Test	ISO 23908	Meets standard

No deviations from recognized consensus ISO standards were identified, except where the design of the device resulted in a modified method or acceptance criterion.

Additionally, performance testing other than to the above ISO Standards was performed on the device to verify the modified device against the currently cleared device. The device complies with the acceptance criteria established based on the predicate, as shown in the table below:

Table 5.6: Performance Testing per Internal Standards

Performance Test	Results
Sheath Activation	Meets acceptance criteria
Sheath Deactivation	Meets acceptance criteria
Needle Penetration	Meets acceptance criteria
Manual Sheath Activation	Meets acceptance criteria
Measurements	Meets acceptance criteria
Simulated Use Study	Passed

Performance testing demonstrates that the new Terumo SurGuard®3 Safety Hypodermic Needle conforms to the recognized consensus ISO standards (ISO 7864 and ISO 23908) and meets internal standards acceptance criteria. Therefore, it is substantially equivalent to the predicate device and is acceptable for clinical use throughout the shelf life.

Biocompatibility

In accordance with ISO 10993-1, the SurGuard 3 (Short Sheath 2) is classified as: Externally Communicating Device, Circulating Blood, Limited Duration of Contact (≤24hr). This classification was the same as the predicate and reference devices (K122249 and K121607).

All of the subject device's materials are the same as the predicate and reference devices (K122249 and K121607). These devices have the same intended use, body contact, and contact duration classification based on ISO 10993-1:2009. We conclude, therefore, that the subject device is biocompatible for its intended use.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11137-1:2006, *Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.* The Terumo SurGuard®3 Safety Hypodermic Needle is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, taking into account the modifications to the previous device, and it was determined that there were no new issues of safety or effectiveness.

J. CLINICAL TESTS (807.92(b)(2))

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

K. CONCLUSION (807.92(b)(3))

In summary, the SurGuard 3 (Short Sheath 2), subject of this Special 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the current device:

K122249 – Terumo SurGuard®3 Safety Hypodermic Needle, manufactured by Terumo (Philippines) Corporation