K121607

NOV 8 2012

510(k) SUMMARY

Prepared for : TERUMO (PHILIPPINES) CORPORATION
124 East Main Avenue, Laguna Technopark,
Binan, Laguna,Philippines

Prepared by : Ma. Cristina Faderagao – Supervisor, Regulatory Affairs
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Date prepared : February 10, 2012

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Terumo Medical Corporation
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Elkton, MD 21921
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A. DEVICE NAME

Proprietary Name
TERUMO® NEEDLE

Classification Name
Hypodermic Single Lumen Needle (880.5570)

Product Code: FMI

Classification: Class II

Common Name: Hypodermic Needle

B. INTENDED USE

The TERUMO® Needle is a hypodermic single lumen needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

C. DEVICE DESCRIPTION

The TERUMO® NEEDLE is a hypodermic sterile single lumen needle, consisting of a stainless tube that is sharpened at one end and at the other end joined to a female luer connector (hub) designed to be connected with a male connector (nozzle) of a piston syringe or an intravascular administration set.

Product Code	Hub Color	Needle Ø (Gauge and mm)	Needle Length (inch – mm)	Wall thickness	Needle Bevel
NN-1825R	Pink	18G – 1.20mm	1" – 25mm	Thin Wall	Regular Bevel
NN-1838R	Pink	18G – 1.20mm	1 ½" – 38mm	Thin Wall	Regular Bevel
NN-1925R	Cream	19G – 1.10mm	1" – 25mm	Thin Wall	Regular Bevel
NN-1938R	Cream	19G – 1.10mm	1 ½" – 38mm	Thin Wall	Regular Bevel
NN-2025R	Yellow	20G – 0.90mm	1" – 25mm	Ultra Thin Wall	Regular Bevel
NN-2025V	Yellow	20G – 0.90mm	1" – 25mm	Regular Wall	Regular Bevel
NN-2038R	Yellow	20G – 0.90mm	1 ½" – 38mm	Ultra Thin Wall	Regular Bevel
NN-2125R	Green	21G – 0.80mm	1" -25mm	Ultra Thin Wall	Regular Bevel
NN-2138R	Green	21G – 0.80mm	1 ½" – 38mm	Ultra Thin Wall	Regular Bevel
NN-2225R	Black	22G – 0.70mm	1" – 25mm	Ultra Thin Wall	Regular Bevel
NN-2238R	Black	22G – 0.65mm	1 ½" – 38mm	Ultra Thin	Regular

				Wall	Bevel
Product Code	**Hub Color**	**Needle ∅ (Gauge and mm)**	**Needle Length (inch – mm)**	**Wall thickness**	**Needle Bevel**
NN-2325R	Blue	23G – 0.65mm	1" – 25mm	Ultra Thin Wall	Regular Bevel
NN-2338R	Blue	23G – 0.65mm	1 ½" 38mm	Ultra Thin Wall	Regular Bevel
NN-2516R	Orange	25G – 0.50mm	5/8" – 16mm	Ultra Thin Wall	Regular Bevel
NN-2522R	Orange	25G – 0.50mm	7/8" – 22mm	Ultra Thin Wall	Regular Bevel
NN-2525R	Orange	25G – 0.50mm	1" – 25mm	Ultra Thin Wall	Regular Bevel
NN-2538R	Orange	25G – 0.50mm	1 ½" – 38mm	Regular Wall	Regular Bevel
NN-2613R	Brown	26G – 0.45mm	½" – 13mm	Regular Wall	Regular Bevel
NN-2713R	Gray	27G – 0.40mm	½" – 13mm	Regular Wall	Regular Bevel
NN-2732R	Gray	27G – 0.40mm	1 ¼" – 32mm	Regular Wall	Regular Bevel
NN-3025R	Yellow	30G – 0.30mm	1" – 25mm	Regular Wall	Regular Bevel
NN-3013R	Yellow	30G – 0.30mm	½" – 13mm	Regular Wall	Regular Bevel

D. SUBSTANTIAL EQUIVALENCE

The TERUMO® NEEDLE manufactured by Terumo Philippines Corporation is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the following cleared devices:

1. K001572 TERUMO® NEOLUS® Needle manufactured by Terumo Europe, Leuven, Belgium
2. K771203 TERUMO® Hypodermic Needle manufactured by Terumo Medical Corporation, Elkton, Maryland
3. K012646 (30G) TERUMO® Needle manufactured by Terumo Medical Corp, Elkton, MD

Intended Use

The TERUMO® Needle manufactured from Terumo (Philippines) Corporation and predicate devices cleared under K001572, K771203 and K012646 (30G) are hypodermic single lumen needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Principles of Operation / Technology

The TERUMO® Needle manufactured by Terumo (Philippines) Corporation and the predicate devices cleared under K001572 manufactured by Terumo Europe N.V. Belgium, and K771573 and K012646 (30G) manufactured by Terumo Medical Corporation, USA are all operated manually.

Design and Materials

The TERUMO® Needle manufactured by Terumo (Philippines) Corporation and the predicate devices cleared under K001572 manufactured by Terumo Europe N.V. Belgium, and K771573 and K012646 (30G) manufactured by Terumo Medical Corporation, USA are made up of stainless steel needle that is sharpened at one end and at the other end was attached to a plastic polypropylene hub by means of adhesive.

Performance

The following performance tests were performed on the TERUMO® Needle manufactured by Terumo (Philippines) Corporation:

- Protector Fit
- Adhesive Hold
- Conical Fitting
- Seal Strength

None of the data raises any new issues on safety and effectiveness.

E. Additional Safety Information

Manufacturing controls include visual, functional and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization. The TERUMO® Needle is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The TERUMO® Needle is classified as Externally Communicating Device, Circulating Blood, Limited Duration of Contact (≤24hr.). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO – 10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

F. Conclusion

In summary, the TERUMO® Needle manufactured by Terumo Philippines Corporation is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the following cleared devices:

1. K001572 TERUMO® NEOLUS® Needle manufactured by Terumo Europe, Leuven, Belgium

2. K771203 TERUMO® Hypodermic Needle manufactured by Terumo Medical Corporation, Elkton, Maryland

3. K012646 (30G) TERUMO® Needle manufactured by Terumo Medical Corporation, Elkton, Maryland

There is no significant change that raises any new issues on safety and effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: November 8, 2012

Terumo Medical Corporation
Ms. Sandi Hartka
Manager, Regulatory Affairs
950 Elkton Boulevard
Elkton, Maryland 21921

Re: K121607
Trade/Device Name: Terumo® Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 2, 2012
Received: November 5, 2012

Dear Ms. Hartka:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson

Digitally signed by Anthony D. Watson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.08 11:16:45 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121607

Device Name: TERUMO® Needle

Indications for Use:

The TERUMO® Needle is a hypodermic single lumen needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121607