K063613

Section II. 510 (k) Summary and Certification
Terumo® Syringe with/without needle
Terumo (Philippines) Corporation

DEC 26 2006

510k Summary

Device Name

Proprietary Name: TERUMO® Syringe without Needle

Classification Name: Syringe, Piston with or without hypodermic single lumen needle

Common Name: Hypodermic Syringe with/without needle

Intended Use
The Terumo Syringe with/without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

Note: This is the same intended use as the predicate device, Terumo Syringe with/without needle cleared under K023271 and K051864.

Device Description
The Terumo 30 and 60cc/mL Syringes consist of 3 main parts, a barrel, plunger, and gasket. Barrel is made from polypropylene and is designed with clear graduations and figures for easy use. The gasket is made from a highly inert thermoplastic elastomer material. The syringes are individually packed in a peel blister that ensures the sterility of the device until the package is opened. The product is sterilized by electron beam sterilization. The product is for single use only and is not intended for reuse.

Principles of Operation/Technology
The 30 and 60cc/mL Terumo Syringes without needle are manually operated.

Materials
The materials used in the 30 and 60cc/mL Terumo Syringes without needle are substantially equivalent to the materials used in the predicate Terumo Syringe with/without needle devices cleared under K023271 and K052034.

Specifications

PRODUCT DESCRIPTION
30cc/ml luer slip syringe
30cc/ml luer lock syringe
30cc/ml eccentric luer syringe
60cc/ml luer lock syringe
60cc/ml eccentric luer syringe
60cc/ml catheter tip syringe

Performance

The Terumo Syringe without needle, 30 and 60cc/mL submitted in this premarket notification was subjected to the following tests:

- Leakage (Aspiration and Injection)
- Plunger Mobility
- Tip-hub fitting
- Gasket fit
- Nominal graduation capacity
- Plunger stopper strength
- Dead Space
- Conical fitting

Substantial Equivalence

The 30 and 60cc/mL Terumo Syringes without needle are substantially equivalent in intended use, materials, design, technology and principles of operation and performance to cleared Terumo Syringes with/without needle cleared under K023271 and K052034. Any differences raise no new issues of safety and effectiveness.

Additional Safety Information

Manufacturing controls included visual, functional, dimensional and sterility tests.

The Terumo Syringe without needle 30 and 60cc/mL are classified as an Externally Communicating Device, Limited contact. 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 10993-1' "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ISO 11137-1995, Medical Devices – Validation and Routine control of Radiation Sterilization. The device is sterilized to a SAL of 10^{-6}.

Submitter Information

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Prepared for: Terumo (Philippines) Corporation
#124 East Main Ave., Laguna Technopark,
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Date Prepared: December 4, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K063613
Trade/Device Name: TERUMO Syringe with/without Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: December 4, 2006
Received: December 12, 2006

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name:____***TERUMO® Syringe with/without Needle***_____

Indications For Use:

The Terumo syringe with/without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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