

AUG 16 2005

K052034

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### 510k Summary

#### Device Name

Proprietary Name: TERUMO® Syringe with/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 (K023271).

#### Device Description

The 1ml Terumo Syringe with/without Needle consists of 3 main parts or 4 parts, i.e., a barrel, plunger, gasket and a hypodermic needle (for with needle type). 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 needle is made from stainless steel. The 1 ml Terumo Syringe with/without Needle is individually packed in 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 1ml Terumo Syringe with/without needle is operated manually.

#### Materials

The materials used in the 1ml Terumo Syringe with/without needle are substantially equivalent to the materials used in the predicate Terumo Syringe with/without needle device cleared under K023271.

#### Specifications

PRODUCT DESCRIPTION
1ml Luer Slip Tip syringe without needle
1 ml Luer Slip Tip syringe with 23g x 1" needle
1 ml Luer Slip Tip syringe with 25g x 5/8" needle
1ml Luer Slip Tip syringe with 25g x 1" needle
1 ml Luer Slip Tip syringe with 26g x 3/8" needle
1 ml Luer Slip Tip syringe with 26g x 1/2" needle
1 ml Luer Slip Tip with 27g x 1/2" needle

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Section II. 510(k) Summary and Certification  
Special 510(k) – TERUMO® Syringe with/without Needle  
Terumo (Philippines) Corporation

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Performance

The 1ml Terumo Syringe with/without needle submitted in this premarket notification was subjected to the following tests:

- Leakage (Aspiration and Injection)
- Plunger Mobility
- Plunger Gasket Fit
- Plunger Stopper Strength
- Deadspace
- Nominal Graduation Capacity
- Packaging Seal Strength

Substantial Equivalence

The 1ml Terumo Syringe with/without needle is substantially equivalent in intended use, materials, design, technology and principles of operation and performance to cleared Terumo Syringes with/without needle cleared under K023271. Any differences raise no new issues of safety and effectiveness.

Additional Safety Information

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

The 1ml Terumo Syringe with/without needle is 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

Prepared by: Barbara Smith  
Sr. Regulatory Affairs Specialist  
Terumo Medical Corporation  
950 Elkton Boulevard  
Elkton, Maryland 21921

Prepared for: Terumo (Philippines) Corporation  
#124 East Main Ave., Laguna Technopark,  
Biñan, Laguna, Philippines 4026

Date Prepared: July 26, 2005

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AUG 16 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Barbara Smith  
Senior Regulatory Affairs Specialist  
Terumo Medical Corporation  
125 Blue Ball Rd.  
Elkton, Maryland 21921

Re: K052034

Trade/Device Name: Terumo Syringe with/without needle  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Hypodermic Syringe with/without needle  
Regulatory Class: II  
Product Code: FMF  
Dated: July 27, 2005  
Received: July 29, 2005

Dear Ms. Smith:

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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

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)

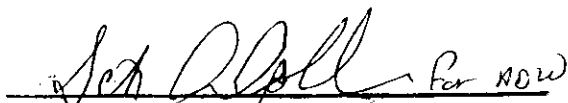
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K052034