K023271

DEC 1 8 2002

510(k) Summary

Submitter Information:

Name and Address:
Terumo (Philippines) Corporation
#124 East Main Ave. Laguna Technopark,
Biñan, Laguna, Philippines 4026

Contact Person:
Ms. Sandi Hartka
Manager Regulatory Affairs
Terumo Medical Corporation
950 Elkton Blvd.,
Phone Number: 410-392-7243
Fax Number: 410-398-6079

Device Name:

Propriety Name: Terumo Syringe with/without Needle
Common Name: Piston Syringe, Disposable Syringe
Classification Name: Syringe, Piston with or without Hypodermic Single Lumen Needle

Predicate Device:

The Terumo Syringe with/without needle that is the subject of this premarket notification is substantially equivalent to the predicate device, Terumo Medical Corporation Hypodermic Syringe, which is legally marketed and was cleared by FDA (K980181).

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.

Principle of Operation and Technology:

Each Terumo Syringe with/without needle is designed for manual use therefore it is operated manually.

Design and Materials

The Terumo Syringe with/without needle consists mainly of 3 parts or 4 parts: a barrel, a plunger, a gasket and a needle (for the 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. This material facilitates smooth movement of the plunger and aids the user in controlling dosage. The needle is made from stainless steel and the needlepoint is carefully designed to minimize resistance at the skin surface and aids in smooth, easy insertion. The Terumo Syringe with/without Needle is individually packed in peel blister that ensures the sterility of the device until the package is opened.

Performance Evaluations:

The Terumo Syringe with/without needle submitted in this premarket notification was subjected to the following tests to demonstrate the safety and efficacy of the device:

- Cleanliness
- Leakage Test
- Sliding Resistance
- Plunger and Gasket Fit Force
- Nozzle-needle Fit Force
- Initial Movement Force
- Stopper Force
- Dead Space
- Equal to Nominal Capacity Graduation Tolerance
- Between Main Capacity Graduation Tolerance
- Primary Container Seal Strength
- Silicone Amount Determination
- Elution Test Method
- Analysis of Heavy Metals
- Determination of pH

Specifications:

PRODUCT	SYRINGE SIZES	NEEDLE GAUGE	EXPOSED NEEDLE LENGTH
Terumo Syringe With/without Needle	3 cc, 5 cc, 10 cc and 20 cc Terumo syringe	Gauges 20 – 27	16 mm (5/8") to 38 mm (1 ½)
Terumo Disposable Hypodermic Syringe (predicate device, K980181)	3 cc, 5cc, 10 20 cc hypodermic syringe	Gauges 18 – 24 Gauges 25 – 27	19 mm (3/4) to 38 mm (1 ½) 13 mm (1/2") to 25 mm (1")

Substantial Equivalence Comparison:

The Terumo Syringe with/without needle is substantially equivalent to the predicate Terumo Medical Corporation Hypodermic Syringe as follows:

- Intended Use: Both Terumo Syringe with/without Needle and the predicate Terumo Disposable Hypodermic Syringe, with or without hypodermic single lumen needle is intended to be used for injecting fluids or withdrawing fluids from the body.

- Principles of Operation: Terumo Syringe with/without Needle and the cleared Terumo Disposable Hypodermic Syringe (K980181) are operated manually.

- Design and Materials: The design of the Terumo Syringe with/without Needle and the predicate Terumo Disposable Hypodermic Syringe is basically the same. Both devices are comprised of a barrel, plunger and gasket (and needle) that are blister packed.

  Both Terumo Syringe with/without Needle and the predicate Terumo Disposable Hypodermic Syringe is made of polypropylene and thermoplastic elastomer. The materials used in the molding of the devices are the same relative to device functioning. Any difference in these materials does raise any new issues of safety and/or effectiveness.

- Performance: The Terumo Syringe with/without Needle has been demonstrated to be safe and effective during handling and for the duration if its expiration. The Terumo Syringe with/without Needle is substantially equivalent to the predicate Terumo Disposable Hypodermic Syringe.

Substantial Equivalence Summary:

In summary, the Terumo Syringe with/without Needle and the predicate Terumo Disposable Hypodermic Syringe are substantially equivalent in intended use, principles of operation, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety or effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with ISO 11137 to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Performance evaluations were conducted on aged and non-aged devices to ensure that the aging process does not adversely affect the performance of the device.

Conclusion:

In summary, the Terumo Syringe with/without Needle is substantially equivalent in intended use, operational principle, design and materials, and performance to the predicate Terumo Disposable Hypodermic Syringe (K980181).

Terumo (Phils.) Corporation's Statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

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

Re: K023271
Trade/Device Name: Terumo Syringe with/without Needle
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 9, 2002
Received: October 1, 2002

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 (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023271

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.

Geraldine A. Pasaba
Regulatory Affairs Officer
Terumo (Philippines) Corporation

(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: K023271

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)