K083514

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

MAY 22 2009

Submitter Information

Prepared for: TERUMO EUROPE N.V.
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Date prepared: November 2008

1. Device Name

Proprietary Name

Terumo® Syringe with/without Needle

Classification Name

Piston syringe (80FMF)

21CFR, Section 880.5860

Classification: Class II

Common Name

Sterile hypodermic syringe with/without needle

2. Reason for Submission
New Device

3. Intended Use

The Terumo Syringe with/without needle is a sterile hypodermic syringe for single use, intended for the aspiration of fluids and blood, or for the injection of fluids immediately after filling.

4. Description & Materials

The Terumo Syringe with/without needle is a hypodermic standard piston syringe, available in volumes from 1 ml, 2 ml, 5 ml, 10 ml and 50 ml, with a luer taper tip for single use, made of plastic material and a synthetic rubber gasket. The needle is made from stainless steel.

Syringe sizes	Needle gauges	Exposed needle lengths
1, 2 (including special graduations), 5, 10, 50 ml	20 – 26G	12 mm (½") – 40 mm (1 ½")

5. Technology/Principles of operation

The Terumo Syringe with/without needle is operated manually.

6. Performance

The Terumo syringe with/without needle was tested in accordance with EN ISO 7886-1 (1993).

For the needle properties, reference is made to the cleared Neolus Needles compared to in the submitted file K001572. In accordance with the new requirements stipulated in EN ISO 10993-4 (2002) and its amendment (2006) the hypodermic needles were also subjected to additional hemocompatibility testing. A declaration for compliance with the requirements of these tests can be found on page 177.

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

7. Substantial Equivalence

The "Terumo Syringe with/without Needle", manufactured by Terumo Europe N.V., is submitted in this 510(k) file is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the following devices:

1. Terumo Syringe with/without needle", manufactured by Terumo (Philippines) Corporation (K023271, K052034, K063613).
2. 50 ml Terumo Syringe for administration of UV sensitive medicines, manufactured by Terumo Europe N.V. (K070264)

Any differences raise no new issues of safety and effectiveness.

8. Additional Safety Information

The sterility of the Terumo Syringe with/without needle is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide sterilization" and ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels and Ethylene Chlorohydrin residual levels resulting from EtO sterilization are in compliance with ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The device is tested for biocompatibility requirements in accordance with the tests stipulated in EN ISO 10993-1, "Biological Evaluation of Medical Devices. Part-1: Evaluation and testing." The results of the testing demonstrate that the device is biocompatible.

The expiration dating for the Terumo Syringe with/without needle has been established at 5 years.

III. DRAFT LABELLING

III.1. Blister paper unit packaging
III.2. Unit box
III.3. Label unit box
III.4. Shipping carton
III.5. Label shipping carton

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. M.J. Aerts
Regulatory Affairs Manager
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B-3001 LEUVEN – BELGIE
BELGIUM

MAY 22 2009

Re: K083514
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: May 7, 2009
Received: May 11, 2009

Dear Ms. Aerts:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Terumo® Syringe with/without needle

Indication For Use:

The Terumo Syringe with/without needle is a sterile hypodermic syringe for single use, intended for the aspiration of fluids and blood, or for the injection of fluids immediately after filling.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

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

510(k) Number: K083514