

APR - 2 1998

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
PERTAINING TO  
SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: Terumo Disposable Hypodermic Syringe or similar proprietary name

Classification Name: Syringe, piston

**INTENDED USE**

The Terumo Disposable Hypodermic Syringe, with or without hypodermic single lumen needle, is used for injecting fluids into or withdrawing fluids from the body. The syringe is designed for manual use.

Note: This is the same intended use as the Terumo Hypodermic Syringe cleared under K771205.

**DESCRIPTION**

The Terumo Disposable Hypodermic Syringe, with or without a hypodermic single lumen needle, is a sterile, single use, standard piston syringe, designed for manual use. The syringe is available in 3, 5, 10, 20, 30 and 60 cc/ml volumes, with luer slip, luer lock, eccentric slip tip, or catheter tip configurations.

The Terumo Disposable Hypodermic Syringe will be sold by prescription only and labeling will bear the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

**SUBSTANTIAL EQUIVALENCE**

The Terumo Disposable Hypodermic Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Hypodermic Syringe (K771205).

## SECTION II: Summary of Safety and Effectiveness

### PRINCIPLE OF OPERATION/TECHNOLOGY

The Terumo Disposable Hypodermic Syringe and the cleared Terumo Hypodermic Syringe (K771205) are both operated manually.

### DESIGN/MATERIALS

The materials used to construct the Terumo Disposable Hypodermic Syringe are the same materials used for the cleared Terumo Hypodermic Syringe (K771205). The Terumo Disposable Hypodermic is substantially equivalent in design to the cleared Terumo Hypodermic Syringe (K771205).

### SPECIFICATIONS

The Terumo Disposable Hypodermic Syringe, with or without hypodermic single lumen needle, is available in 3, 5, 10, 20, 30 and 60 cc/ml volumes, with luer slip, luer lock, eccentric slip tip or catheter tip configurations.

Minor design changes have been implemented to produce The Terumo Disposable Hypodermic Syringe. These minor design changes are as follows:

- The outer diameter of the barrel has decreased
- The overall length of the barrel has decreased
- The wall of the barrel is slightly thinner
- The flange height is slightly less
- The plunger rib cross section has been very slightly reduced
- The gasket height has been lessened

NOTE: The inner diameter of the Terumo Disposable Hypodermic Syringe barrel has not changed from the cleared predicate device barrel inner diameter (Terumo Hypodermic Syringe K771205).

### PERFORMANCE

The performance of the Terumo Disposable Hypodermic Syringe is substantially equivalent to the performance of the cleared Terumo Hypodermic Syringe (K771205), and will meet the same range of performance acceptance criteria.

## SECTION II: Summary of Safety and Effectiveness

The Terumo Disposable Hypodermic Syringe complies with ISO 594-1:1986, Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment--Part 1: General requirements and Part 2: Lock fittings.

The Terumo Disposable Hypodermic Syringe complies with Section II, Item #3 (barrel volume) of the Standard for Disposable Hypodermic Syringes, Notification No. 442 of the Japan Ministry of Health and Welfare: December 28, 1970.

The Terumo Disposable Hypodermic Syringe also complies with specific sections of ISO 7886-1 Guidance for Sterile Hypodermic Syringes for Single Use, Part 1: Syringes for manual use, as indicated in the table below.

	APPLICABLE STANDARD
Leakage Aspiration Injection	ISO 7886-1
Plunger Mobility/Gasket Slide	ISO 7886-1
Dead Space	ISO 7886-1
Silicone Quantity	ISO 7886-1
Graduation Location	ISO 7886-1
Conical Fitting/Luer Taper	ISO 594-1, ISO 594-2
Barrel Volume	Japan Ministry of Health & Welfare, No. 442: 12/28/70

### ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the European Standard, EN 556: Sterilization of Medical Devices - Requirements for Medical Devices to Be Labeled Sterile, to provide a Sterility Assurance Level (SAL) of  $10^{-6}$ .

Manufacturing control test methods include: functional and sterility tests.

LAL testing is performed on production samples from of every lot number.

## SECTION II: Summary of Safety and Effectiveness

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." [External Communicating Devices, Blood Path Indirect, Limited Duration of Contact (<24 hours).] The blood contacting materials were found to be biocompatible.

The expiration dating for the Terumo Disposable Hypodermic Syringe has been established to be 5 years, or 60 months.

### CONCLUSION

The Terumo Disposable Hypodermic Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Hypodermic Syringe. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Date Prepared: January 16, 1998

Prepared by: Kristine Wagner  
Regulatory Affairs Specialist

Prepared for: Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Phone (410) 392-7241 or (410) 392-7231  
Fax (410) 398-6079



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kristine Wagner  
Regulatory Affairs Specialist  
Terumo® Medical Corporation  
Regulatory Affairs Department  
125 Blue Ball Road  
Elkton, Maryland 21921

APR - 2 1998

Re: K980181  
Trade Name: Terumo Disposable Hypodermic Syringe  
Regulatory Class: II  
Product Code: FMF  
Dated: January 16, 1998  
Received: January 20, 1998

Dear Ms. Wagner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

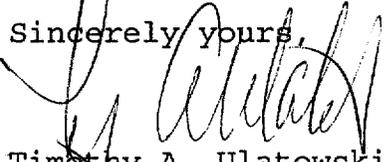
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K980181

Device Name: Terumo Disposable Hypodermic Syringe

Indications For Use:

The Terumo Disposable Hypodermic Syringe, with or without hypodermic single lumen needle, is used for injecting fluids into or withdrawing fluids from the body. The syringe is designed for manual use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Rafaela Cicante*  
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(Signature Sign-Off)  
Director, Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K980181

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)