

SEP 9 1999

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

Device Name: TERUMO® U-100 Insulin Syringe, or similar proprietary name  
Classification Name: Piston syringe with fixed hypodermic single lumen needle

**INTENDED USE**

The TERUMO® U-100 Insulin Syringe, with fixed hypodermic single lumen needle, is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended particularly for the aspiration and injection of insulin.

**DESCRIPTION**

The Terumo U-100 Insulin Syringe is a sterile, single use piston syringe with a fixed hypodermic single lumen needle, designed for manual use. The syringe is available in 1/2cc and 3/10cc volumes with a 30 gauge by 3/8 inch fixed hypodermic single lumen needle.

**SUBSTANTIAL EQUIVALENCE**

The Terumo U-100 Insulin Syringe submitted in this 510k, is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Medical Corporation U-100 Insulin syringe (K822083). There is no intended change in how this device is used.

With respect to the 30G x 3/8" cannula, the Terumo U-100 Insulin Syringe submitted in this 510k is substantially equivalent to the cleared Becton Dickinson® Ultra Fine II Insulin Syringe with 30G x 5/16" cannula (K955235).

**PRINCIPLE OF OPERATION/TECHNOLOGY**

The Terumo U-100 Insulin Syringe is operated manually.

**MATERIALS**

The materials used in the manufacture of the Terumo U-100 Insulin Syringe are the same materials used in the manufacture of the predicate device.

**PERFORMANCE**

The performance of the TERUMO® U-100 Insulin Syringe submitted in this 510k is equivalent to the performance of the cleared TERUMO U-100 Insulin Syringe (K822083) and to the Becton-Dickinson® Ultra Fine II Insulin Syringe (K955235).

## SECTION II: Summary of Safety and Effectiveness

Testing was performed to demonstrate the substantial equivalence of the TERUMO U-100 Insulin Syringe with 30G x 3/8" cannula to the cleared Terumo U-100 Insulin Syringe and the B-D Ultra Fine II Insulin Syringe with 30G x 5/16" cannula.

### **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.

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 U-100 Insulin Syringe has been established to be 5 years, or 60 months.

### **CONCLUSION**

The Terumo U-100 Insulin Syringe with 30 gauge x 3/8 inch cannula submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo U-100 Insulin Syringe (K822083), and the B-D Ultra Fine II Insulin Syringe with 30 gauge x 5/16 inch cannula. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Terumo's statement that these devices are 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 whatsoever to be the basis for a patent infringement action.

Date Prepared: July 30, 1999  
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  
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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

Re: K992802  
Trade Name: Terumo U-100 Insulin Syringe  
Regulatory Class: I  
Product Code: FMF  
Dated: August 18, 1999  
Received: August 19, 1999

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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

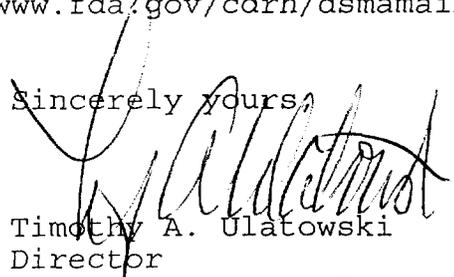
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4690. 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): K 992802

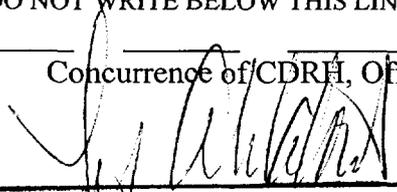
Device Name: TERUMO® U-100 INSULIN SYRINGE

**Indications For Use:**

The TERUMO® U-100 Insulin Syringe, with fixed hypodermic single lumen needle, is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended particularly for the aspiration and injection of insulin.

(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 Dental, Infection Control,  
and General Hospital Devices

510(k) Number K 992802

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use