

APR - 2 1998

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

Proprietary Device Name: Terumo Allergy Syringe or similar proprietary name
Classification Name: Syringe, piston with fixed hypodermic single lumen needle

INTENDED USE

The Terumo Allergy Syringe is intended for the preparation/mixing of allergenic extracts/prescribed substances, the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. The syringe is designed for manual use. These allergy syringes will be sold by prescription only, and the labeling will bear the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

DESCRIPTION

The Terumo Allergy Syringe with fixed hypodermic single lumen needle is a sterile, single use, standard piston syringe, designed for manual use. The syringe is available in 1cc volumes with 23G, 26G and 27G, 1/2" and 3/8" fixed hypodermic single lumen needles. These needles have either a regular or intradermal bevel. See following chart:

PROPOSED:

NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL	SYRINGE PACKAGING
23	1/2"	Regular	Trays of 25
26	3/8"	Regular	Trays of 25
27	1/2"	Regular	Individual
27	1/2"	Regular	Trays of 25
27	1/2"	Intradermal	Trays of 25
27	3/8"	Intradermal	Trays of 25

PREDICATE:

NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL	SYRINGE PACKAGING
23	1"	Regular	Individual
25	5/8"	Regular	Individual
26	1/2"	Regular	Trays of 25
26	3/8"	Intradermal	Trays of 25
27	1/2"	Regular	Trays of 25
27	3/8"	Intradermal	Trays of 25

SECTION II: Summary of Safety and Effectiveness

SUBSTANTIAL EQUIVALENCE

The Terumo Allergy syringe submitted in this 510k is substantially equivalent in intended use, design, specifications, technology/principles of operation, materials and performance to the cleared B-D® Allergy syringe which is the subject of K941657.

PRINCIPLE OF OPERATION/TECHNOLOGY

The Terumo Allergy Syringe and the B-D Allergy Syringe are both operated manually or by a manual process.

MATERIALS

MATERIALS	PROPOSED	PREDICATE
Barrel	Polypropylene	Polypropylene
Plunger	Polystyrene	Polystyrene
Gasket	Thermoplastic elastomer	Unknown
Needle	Stainless steel	Unknown

PERFORMANCE

The performance of the Terumo Allergy Syringe is substantially equivalent to the performance of the cleared B-D® Allergy Syringe (K941657).

The following tests were performed demonstrating the substantial equivalence of the Terumo Allergy Syringe submitted in this 510k to the B-D® Allergy Syringe (K941657).

- Volume
- Cannula/barrel adherence
- Maximum penetration force
- Leakage
- Aspiration - initial breakaway force
- Aspiration
- Injection force
- Residual volume

SECTION II: Summary of Safety and Effectiveness

ADDITIONAL SAFETY INFORMATION

The sterility of the product is assured using a sterilization method validated and qualified in accordance with the ISO 11137- "Sterilization of Healthcare Products Requirements for Validation and Routine Control - Radiation Sterilization" to a sterility assurance level (SAL) of 10^{-6} .

Additionally each lot is monitored with calibrated Harwell Red Perspex 4034 dosimeters to determine the Gamma radiation dose delivered. Critical parameters, such as exposure time and dose delivery interruption are confirmed to comply with procedure.

Manufacturing control test methods include functional tests.

LAL testing is performed on production samples from 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).] days). The blood contacting materials were found to be biocompatible.

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

CONCLUSION

The Terumo Allergy syringe submitted in this 510(k) is substantially equivalent in intended use, design, specification, technology/principles of operation, materials and performance to the cleared B-D® Allergy syringe which is the subject of K941657. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Date Prepared	February 27, 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

APR - 2 1998

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

Re: K980796
Trade Name: Terumo Allergy Syringe
Regulatory Class: II
Product Code: FMF
Dated: February 27, 1998
Received: March 2, 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 (Premarket 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 the Act for devices under the Electronic

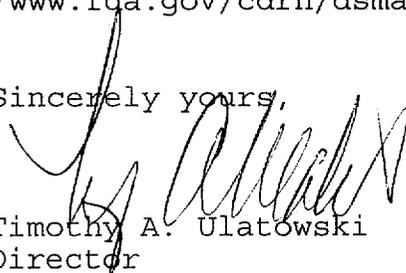
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Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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" (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): K980796

Device Name: Terumo Allergy Syringe

Indications For Use:

The Terumo Allergy Syringe is intended for the preparation/mixing of allergenic extracts/prescribed substances, the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This 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)

Adina Cruz
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980796

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____