

NOV 30 1998

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

Proprietary Device Name: TERUMO® VENOJECT® Luer Adapter or similar
proprietary name
Classification Name: Blood Specimen Collection Device

INTENDED USE

The Terumo Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. When blood samples are to be obtained with a single venipuncture, the luer adapter is a conduit between the collection needle and the collection container.

DESCRIPTION/SPECIFICATIONS

The Terumo Venoject Luer Adapter is a sterile, single use device consisting of a cannula joined to a female connector (hub) which is connected to a luer taper. The cannula is covered with a synthetic isoprene rubber tip for stopping blood flow. When blood is collected, the collection container is placed over the cannula, pushing the rubber tip back, allowing blood flow. When the collection container is removed, the rubber tip extends back over the cannula, stopping blood flow. The luer adapter has no direct patient contact.

SUBSTANTIAL EQUIVALENCE

The Terumo Venoject Luer Adapter submitted in this 510k is substantially equivalent in intended use, design, principle of operation, and materials to the cleared B-D® Vacutainer® Luer Adapter which is the subject of K931367.

PRINCIPLE OF OPERATION/TECHNOLOGY

The Terumo Venoject Luer Adapter and the B-D Vacutainer Luer Adapter are both operated manually.

MATERIALS

MATERIALS	PROPOSED	PREDICATE
Needle	Stainless Steel	Stainless Steel
Hub	Polypropylene	Polystyrene
Rubber Tip	Synthetic Isoprene Rubber	Dipped Latex Rubber
Cap	Polypropylene	Polypropylene
Case	Polypropylene and polyethylene	Polyethylene

PERFORMANCE

The performance of the TERUMO® VENOJECT® Luer Adapter has been evaluated and the device performs according to specification.

The following tests were performed to evaluate the performance of the Terumo Venoject Luer Adapter submitted in this 510k:

- Cannula elasticity
- Cannula/barrel adherence
- Bending strength
- Visual
- Dimensional
- Extraction

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 Radics plastic dosimeters to determine the Gamma radiation dose delivered. Critical parameters, such as exposure time and dose delivery interruption are confirmed to comply with procedure.

Because this device does not come in direct contact with the patient, biocompatibility screening tests were performed. The results of these screening tests gave no indication that additional biocompatibility testing was necessary.

The expiration dating for the TERUMO® VENOJECT® Luer Adapter has been established to be 30 months.

SECTION II: Summary of Safety and Effectiveness

CONCLUSION

The Terumo Venoject Luer Adapter submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation, and materials to the cleared B-D® Vacutainer® Luer Adapter which is the subject of K931367. Differences between the devices cited in this section are not significant and do not raise any new issues of safety or effectiveness.

Date Prepared	September 30, 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



NOV 30 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kristine Wagner
Regulatory Affairs Specialist
TERUMO MEDICAL CORPORATION
125 Blue Ball Road
Elkton, MD 21921

Re: K983490
Trade Name: TERUMO® VENOJECT® Luer Adapter
Regulatory Class: II
Product Code: 75 JKA
Dated: September 30, 1998
Received: October 05, 1998

Dear Ms. Wagner:

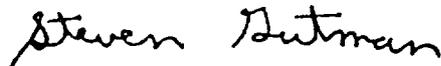
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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 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) 594-4588. 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/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 983490

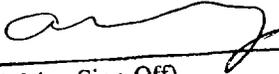
Device Name: TERUMO® VENOJECT® Luer Adapter

Indications For Use:

The Terumo Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. When blood samples are to be obtained with a single venipuncture, the luer adapter is a conduit between the collection needle and the collection container.

(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 Clinical Laboratory Devices
510(k) Number K 983490

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use