MAY 2 8 1999

K991088

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21CFR § 807.92

Establishment:

• Address:	Becton Dickinson VACUTAINER Systems 1 Becton Drive Franklin Lakes, NJ 07417-1885
• Registration Number:	2243072
• Contact Person:	Andrea Hroncich Regulatory Affairs Associate Telephone no.: 201-847-6173 Fax No. 201-847-4858
• Date of Summary:	March 31, 1999
• Trade Name:	VACUTAINER® Brand Multiple Sample Luer Adapter
• Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection
• Classification:	Class II
• Performance Standards:	None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

- Device Description

The VACUTAINER® Brand Multiple Sample Luer Adapter consists of a male luer-slip fitting which mates with the female connector of other medical devices, and a non-patient (NP) cannula which punctures the stopper of an evacuated tube. The luer hub is injection molded polystyrene to which the stainless steel NP cannula is assembled with epoxy. The hub is threaded at the NP end to allow assembly to a VACUTAINER Brand Needle Holder.

The NP cannula of the multi-sample luer adapter is covered by a sleeve that recovers over the cannula to stop blood flow during collection of multiple tubes. In the principal device, this sleeve is manufactured of latex-free synthetic isoprene rubber.

- Intended Use

The VACUTAINER® Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The VACUTAINER® Brand Luer Adapter is sold by itself and as a component of other VACUTAINER Brand devices.

- Synopsis of Performance Study Results

Functional and Mechanical testing was done to compare the performance of the modified VACUTAINER® Brand Luer Adapter with the new latex-free synthetic isoprene rubber sleeve against both the currently manufactured VACUTAINER® Brand Luer Adapter and the TERUMO® Brand VENOJECT™ Luer Adapter.

Results of the testing demonstrated that the modified VACUTAINER Brand Multiple Sample Luer Adapter with Latex-Free Sleeve performed as well or better than both the currently manufactured VACUTAINER® Brand Multiple Sample Luer Adapter and the TERUMO® Brand VENOJECT™ Luer Adapter.

III. Predicate Device Summary Table

Substantial Equivalence

Based on comparison of the device features, intended use, basic design, technology/principles of operation, materials, and performance, the VACUTAINER® Brand Multiple Sample Luer Adapter with Latex-Free Sleeve can be shown to be substantially equivalent to the commercially available predicate devices indicated in the table below. The predicate devices, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER Systems	VACUTAINER® Brand Multiple Sample Luer Adapter	K931367	5/18/93
Terumo Medical Corporation	TERUMO® Brand VENOJECT™ Luer Adapter	K983490	11/30/98

Andrea Hroncich

Andrea Hroncich
Regulatory Affairs Associate
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company

March 31, 1999
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 1999

Andrea Hroncich
Regulatory Affairs Associate
Beckton Dickinson Vacutainer Systems
1 Becton Drive
Franklin Lakes, NJ 07417

Re: K991088
Trade Name: Vacutainer Brand Multiple Sample Luer Adapter
Regulatory Class: II
Product Code: JKA
Dated: March 31, 1999
Received: April 01, 1999

Dear Ms. Hroncich:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 Gutman

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

B. INDICATIONS FOR USE

510(k) Number (if known): K991088

Device Name: VACUTAINER® Brand Multiple Sample Luer Adapter

Indications for Use:

The VACUTAINER® Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The VACUTAINER® Brand Luer Adapter is sold by itself and as a component of other VACUTAINER Brand devices.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991088

(Please do not Write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use_____

(Per 21 CFR § 801.109)

(Optional format 1-2-96)