JUL 28 1999

K991702

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 21 § 807.92

Establishment:

• Address:	Becton Dickinson VACUTAINER Systems 1 Becton Drive Franklin Lakes, NJ 07417-1885
• Registration Number:	2243072
• Contact Person:	Andrea Hroncich Senior Regulatory Affairs Associate Telephone no.: 201-847-6173 Fax No. 201-847-4858
• Date of Summary:	May 18, 1999

Device

• Trade Name:	MICROTAINER® Brand Chemistry Tubes with MICROGARD™ Closure
• 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 modified MICROTAINER® Brand Chemistry Tubes with MICROGARD™ Closure are non-sterile, single use microcollection tubes. They consist of a polypropylene reservoir with an integral blood collector component, a skirted polyethylene closure with a recessed plug that reduces user exposure to blood.

- Intended Use

The MICROTAINER® Brand Chemistry Tubes with MICROGARD™ Closure are intended to collect, transport, and store skin puncture blood specimens for chemistry determinations requiring serum or heparinized plasma.

- Synopsis of Performance Study Results

Clinical testing was done to compare the performance of the predicate MICROTAINER® Brand Tube, with the principal device, the modified MICROTAINER® Brand Tube with MICROGARD™ Closure.

The first part of the study evaluated the tubes for hemolysis and clotting. The study concluded that the principal device, the modified MICROTAINER® Brand Tube with MICROGARD™ Closure (evaluation tube), demonstrated equivalent or better performance compared to the predicate device, the MICROTAINER® Brand Tube (control tube). The study showed no clotting in any evaluation tube or control tube, and trace hemolysis in only one control tube.

The second part of the study compared the performance of the evaluation tube to a control tube using the Johnson and Johnson Vitros 250 Chemistry Analyzer to measure an array of chemistry analytes in plasma. Results from this study concluded that the principal device, the modified MICROTAINER® Brand Tube with MICROGARD™ Closure, demonstrated equivalent results to the predicate device, the MICROTAINER® Brand Tube for most of the analytes tested. The predicate device demonstrated a positive bias for several analytes, however the bias was not considered clinically significant. The final report can be referenced in Appendix A of this submission.

In conclusion, the data supports a determination of equivalent performance between the modified MICROTAINER® Brand Tube with MICROGARD™ Closure as presented in this submission and the currently marketed predicate device.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the intended use, technology/principles of operation, materials and performance in the first case, and design and materials in the second, the MICROTAINER® Brand Chemistry tubes 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 dates are also identified in the table.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER Systems	MICROTAINER® Brand Tubes	K771370	8/3/77
Becton Dickinson VACUTAINER Systems	MICROTAINER® Brand EDTA Tube with MICROGARD™ Closure	K931368/A	9/28/93

Andrea Hroncich

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

May 18, 1999
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 28 1999

Ms. Andrea Hroncich
Regulatory Affairs Associate
Beckton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

Re: K991702
Trade Name: MICROTAINER® Brand Chemistry tubes with MICROGARD™ Closure
Regulatory Class: II
Product Code: JKA
Dated: May 18, 1999
Received: May 19, 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): K991702

Device Name: MICROTAINER® Brand Chemistry tubes with MICROGARD™ Closure

Indications for Use:

The MICROTAINER® Brand Chemistry tubes with MICROGARD™ Closure are intended to collect, transport, and store skin puncture blood specimens for chemistry determinations requiring serum or heparinized plasma.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991702

(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)