
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: James W. Haynes
Regulatory Affairs Specialist
Telephone No.: 201) 847-5170
Fax No. (201) 847-4858
- Date of Summary: March 31, 1999

Device

- Trade Name: VACUTAINER® Brand CTAD Tube
- 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 the Substantial Equivalence Determination

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 CTAD Tubes are sterile, glass, evacuated blood collection tubes. The tubes contain 0.109M Sodium Citrate as an anticoagulant intended to prevent whole blood from clotting prior to analysis. In addition to citrate, the CTAD tube contains theophylline, adenosine and dipyridamole (inhibitors of platelet activation). The specimen is centrifuged and the plasma portion is analyzed for coagulation parameters to detect clotting time disorders and to monitor patients undergoing anticoagulation therapy.

- **Intended Use:**

The VACUTAINER® Brand CTAD Tube is an evacuated blood collection tube which provides a means of collecting, transporting and processing blood in a closed tube. The CTAD additive, a combination of a buffered sodium citrate, theophylline, adenosine and dipyridamole, provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays.

- **Synopsis of Test Methods and Results**

Clinical evaluations were performed to determine the safety and efficacy of the VACUTAINER® Brand CTAD Tube. The VACUTAINER® Brand CTAD Tube was compared to the currently marketed VACUTAINER® Brand Sodium Citrate Tube. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand CTAD Tube provides clinically equivalent results when compared to the VACUTAINER® Brand Sodium Citrate Tube for Normal Donors and Warfarin Donors. The superior performance of the VACUTAINER® Brand CTAD Tube was distinctly demonstrated for patients undergoing heparin anticoagulant therapy. For the Heparin Donors, the tube demonstrated clinically non-equivalent aPTT, Heparin Xa and Platelet Factor 4 results when compared to the VACUTAINER® Brand Sodium Citrate Tube. These expected results clearly illustrated the effects of the CTAD additive to prevent platelet activation and subsequent release of platelet factor 4. The reduced levels of platelet factor 4 minimized the neutralization of heparin in the sample,

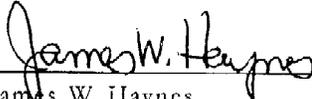
thus leading to longer aPTT clotting times, higher Heparin Xa results and lower Platelet Factor 4 results. This stabilization of heparin in the collected sample allows for a more accurate monitoring of anticoagulant therapy in heparinized patients.

- Substantial Equivalence

Based on comparison of the device features, materials, and intended use, the VACUTAINER® Brand CTAD Tube can be shown to be substantially equivalent to the commercially available predicate device.

The predicate device, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER® Systems	VACUTAINER® Brand Sodium Citrate Tube	N/A	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976


James W. Haynes
Regulatory Affairs Specialist

March 31, 1999
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 19 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. James W. Haynes
Regulatory Affairs Specialist
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

Re: K991120
Trade Name: VACUTAINER® Brand CT AD Tube
Regulatory Class: II
Product Code: JKA
Dated: March 31, 1999
Received: April 2, 1999

Dear Mr. Haynes:

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 (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 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.

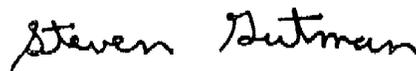
Page 2

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 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): K991120

Device Name: VACUTAINER® Brand CTAD Tube

Indications for Use:

The VACUTAINER® Brand CTAD Tube is an evacuated blood collection tube which provides a means of collecting, transporting and processing blood in a closed tube. The CTAD additive, a combination of a buffered sodium citrate, theophylline, adenosine and dipyridamole, provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991120

(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)