K980414

Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885
(201) 847-4500

MAR - 3 1998

BECTON DICKINSON

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: John A. Schalago
  Regulatory Affairs Specialist
  Telephone no.: 973 - 847 - 6280
  Facsimile no.: 973 - 847 - 4858
- Date of Summary: January 30, 1998

Device Name:

- Trade Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
- Classification Name: Accessory to: Tubes, Vials, Systems, Serum Separators, Blood Collection (75JKA)
- 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" is used in this 510(k) Premarket Notification is limited to the

definition of Substantial Equivalence as 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 Blood Collection Sets and Safety-Lok™ Blood Collection Set is a sterile winged blood collection needles with flexible tubing and a female luer adapter manufactured by Becton Dickinson VACUTAINER Systems, Sumter, South Carolina. The Safety-Lok™ Blood Collection Set is provided with a safety shield for covering the used needle prior to disposal. A male luer adapter is provided on specific reorder numbers. The male luer adapter contains a non-patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided with a protective cap on the end of the female luer adapter.

- Intended Use:

  The VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set are winged blood collection needles with flexible tubing and a female luer adapter intended for venipuncture to obtain blood samples from patients or monitoring blood pressure. The Safety-Lok™ Blood Collection Set is provided with a safety shield for covering the used needle prior to disposal. Some reorder numbers are provided with a male luer adapter. The male luer adapter contains a non-patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided with a protective cap on the end of the female luer adapter.

  The VACUTAINER® Brand Blood Collection Sets and Safety-Lok™ Blood Collection set is also indicated for the intravenous administration of fluids and may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy.

- Synopsis of Test Methods and Results

  Biocompatibility of the VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set has been demonstrated in testing which was performed in accordance with the ISO 10993

Biological Testing requirements. Further, functional performance of the Safety-Lok™ Blood Collection Set has previously been demonstrated in 510(k) Premarket Notifications to the FDA.

- Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand Blood Collection set and VACUTAINER® Brand Safety-Lok™ Blood Collection set are substantially equivalent to the predicate devices described below. This substantial equivalence determination is supported by a comparison of device components, intended use and function.

Manufacturer	Device	K-Number	Clearance Date
Becton Dickinson Infusion Therapy systems	E-Z Set® Intravascular Administration Set	K970259	April 8, 1997
Becton Dickinson Infusion Therapy systems	Safety E-Z Set® Intravascular Administration Set	K970259	April 8, 1997

John A. Schalago

1/30/98

John A. Schalago

Date

Regulatory Affairs Specialist
Regulatory Affairs Department

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

John Schalago
Regulatory Affairs Specialist
Becton Dickinson
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

MAR - 3 1998

Re: K980414
VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
Regulatory Class: II
Product Code: JKA
Dated: January 30, 1998
Received: February 3, 1998

Dear Mr. Schalago:

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 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/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

510(K) NUMBER (IF KNOWN): _____

DEVICE NAME: VACUTAINER® BLOOD COLLECTION SET AND SAFETY-LOK™ BLOOD COLLECTION SET

INDICATIONS FOR USE:

THE VACUTAINER® BRAND BLOOD COLLECTION SETS AND SAFETY-LOK™ BLOOD COLLECTION SET IS A WINGED BLOOD COLLECTION NEEDLE AND FLEXIBLE TUBING FOR VENIPUNCTURE TO COLLECT BLOOD SPECIMENS FROM PATIENTS OR MONITORING BLOOD PRESSURE. THE SAFETY-LOK™ BLOOD COLLECTION SET ALSO CONTAINS A NEEDLE SAFETY SHIELD WHICH MINIMIZES THE POSSIBILITY OF NEEDLESTICKS IF MANUALLY ACTIVATED FOLLOWING BLOOD COLLECTION. THE VACUTAINER® BRAND BLOOD COLLECTION SETS AND SAFETY-LOK™ BLOOD COLLECTION SET IS ALSO RECOMMENDED FOR USE IN PATIENTS WITH SMALL VEINS.

THE VACUTAINER® BRAND BLOOD COLLECTION SETS AND SAFETY-LOK™ BLOOD COLLECTION SET IS ALSO INDICATED FOR THE INTRAVENOUS ADMINISTRATION OF FLUIDS AND MAY BE USED FOR ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO PATIENT SIZE, APPROPRIATENESS FOR THE SOLUTION BEING INFUSED AND DURATION OF THERAPY.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980414

(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)