NOV 1 8 2003

K033350

Attachment 4

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: BD Diagnostics, Preanalytical Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: M. Wendy Ballesteros
  Regulatory Affairs Specialist
  Telephone no.: 201-847-6280
  Fax No. 201-847-4858
- Date of Summary: October 17, 2003

Device

- Trade Name: BD Vacutainer® Safety-Lok™ Administration Set with Filter
- Classification Name: Intravascular Administration Set
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD Vacutainer® Safety-Lok™ Administration Set with Filter is intended for the infusion of fluids. The wing set contains a safety shield that is manually activated once infusion is complete, helping to prevent accidental needle sticks.

- Intended Use

The BD Vacutainer® Safety-Lok™ Administration Set with Filter is a sterile, single-use winged set intended 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. The BD Vacutainer® Safety-Lok™ Administration Set with Filter minimizes the possibility of needlesticks if manually activated following administration.

- Synopsis of Performance Study Results

Extensive mechanical and compatibility testing was performed to demonstrate the device's safety and effectiveness.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD Vacutainer® Safety-Lok™ Administration Set with Filter is shown to be substantially equivalent to the commercially available predicate device indicated in the table below. The predicate device, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson	BD Vacutainer® Safety-Lok™ Blood Collection Set	K980414	March 3, 1998

MW Ballesteros — Oct. 17, 2003

M. Wendy Ballesteros
Regulatory Affairs Specialist
BD Diagnostics, PreAnalytical Systems
Becton Dickinson and Company

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2003

Becton Dickinson Company
M. Wendy Ballesteros
Regulatory Affairs Specialist
BD Diagnostics, Preanalytical Systems
1 Becton Drive
Franklin lakes, New Jersey 07417

Re: K033350
Trade/Device Name: BD Vacutainer® Safety-Lok™ Administration Set with Filter
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 17, 2003
Received: October 24, 2003

Dear Ms. Ballesteros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

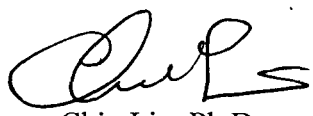
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

B. INDICATIONS FOR USE

510(K) NUMBER (IF KNOWN): _____

DEVICE NAME: BD Vacutainer® Safety-Lok™ Administration Set with Filter

INDICATIONS FOR USE:

The BD Vacutainer® Safety-Lok™ Administration Set with Filter is a sterile, single-use wing set intended for the intravenous administration of fluids and may be used for any patie population with consideration given to patient size, appropriateness for the solution being infus and duration of therapy. The BD Vacutainer® Safety-Lok™ Administration Set with Fil minimizes the possibility of needlesticks if manually activated following administration.

(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 1-2-9

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033350