K022875

SEP 11 2002

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:	Becton Dickinson Vacutainer Systems, *Preanalytical Solutions* 1 Becton Drive Franklin Lakes, NJ 07417-1885
• Registration Number:	2243072
• Contact Person:	M. Wendy Bosshardt Regulatory Affairs Specialist Telephone no.: 201-847-6280 Fax No. 201-847-4858
• Date of Summary:	August 29, 2002

Device

• Trade Name:	BD Vacutainer™ Push Button Blood Collection Set
• Classification Name:	Blood Specimen Collection Devices
• Classification:	Class II
• Performance Standards:	None Established under 514 of the Food, Drug and Cosmetic Act

K022875

II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD Vacutainer™ Push Button Blood Collection Set is for venous blood collection. The wing set contains a needle that will retract into the body of the device when a button is depressed, helping to prevent accidental needle sticks. The retraction of the needle occurs when the user depresses the button.

- Intended Use

The BD Vacutainer™ Push Button Blood Collection Set is a sterile, multiple-sample, single-use winged blood collection set intended for venipuncture to obtain blood specimens from patients. The recommended use of the device is to activate the needle prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of needlestick injury.

- Synopsis of Performance Study Results

Extensive mechanical, simulated use and clinical testing were performed to demonstrate the device's safety and effectiveness.

K022875

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD Vacutainer™ Push Button Blood Collection Set be 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™ Push Button Blood Collection Set	K011984	August 29, 2001

M. Wendy Bosshardt — August 29, 2002

M. Wendy Bosshardt
Date
Regulatory Affairs Specialist
Becton Dickinson Vacutainer Systems, PreAnalytical Solutions
Becton Dickinson and Company

Becton Dickinson and Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Ms. M. Wendy Bosshardt
Regulatory Affairs Specialist
Becton Dickinson & Company
Vacutanier Systems Preanalytical Solutions
1 Becton Drive
Franklin Lakes, New Jersey 07417-1880

Re: K022875
Trade/Device Name: BD VACUTAINER™ Push Button Blood Collection Set
Regulation Number: 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: August 29, 2002
Received: August 30, 2002

Dear Ms. Bosshardt:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
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): K022875

DEVICE NAME: BD VACUTAINER™ PUSH BUTTON BLOOD COLLECTION SET

INDICATIONS FOR USE:

The BD Vacutainer™ Push Button Blood Collection Set is a sterile, multiple-sample, single-use winged blood collection set intended for venipuncture to obtain blood specimens from patients. The recommended use of the device is to activate the needle prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of needlestick injury.

(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)

Patricia Cucuzzella

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

510(k) Number: K022875