K003461

FEB - 1 2001

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: M. Wendy Bosshardt
  Regulatory Affairs Specialist
  Telephone no.: 201-847-6280
  Fax No. 201-847-4858
- Date of Summary: October 27, 2000

Device

- Trade Name: BD Vacutainer™ Passive Shielding Blood Collection Needle
- 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 BD Vacutainer™ Passive Shielding Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The device is designed with an integrated needle holder and a safety shield. The safety shield is automatically activated during blood collection of the first tube. Upon removal of the needle from the venous puncture site, the shield automatically slides up over the needle and locks into place.

- Intended Use

The BD Vacutainer™ Passive Shielding Blood Collection Needle is a sterile, multiple-sample, single-use device intended for venous blood collection. The needle is designed with a passive safety shielding feature and integrated needle holder to aid in the prevention of needle stick injury from both cannula needlepoints. With this passive device, the user automatically activates the safety-shielding feature upon full insertion of the first collection tube. Upon withdrawal of the needle from the venous puncture site no manual manipulation is required to fully activate the safety shield over the cannula. The passive safety shielding mechanism with passive activation has the potential to result in virtually 100% utilization of the safety feature leading to significant reduction in accidental needle stick injury. Passive shielding of the needle cannula upon withdrawal also minimizes the risk of blood splatter.

- Synopsis of Performance Study Results

Mechanical bench testing was performed to confirm the robustness of the design and reliability of the safety shield function.

Simulated use testing was performed by a panel of health care professionals to evaluate function of the safety shield feature in a blood drawing environment. Clinical studies included evaluations of: ease of use, compatibility of tubes, blood splatter and convenience of disposal.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the intended use, technology/principles of operation, materials performance design and materials. BD Vacutainer™ Passive Shielding Blood Collection Needle 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
BDVacutainer Systems	Vacutainer® Brand Blood Collection Needles	Pre-amendment	N/A
BDVacutainer Systems	BD Vacutainer™ Eclipse™ Blood Collection Needle	K-982541	October 28,1998

M. Wendy Bosshardt

M. Wendy Bosshardt
Regulatory Affairs Specialist
Becton Dickinson Vacutainer Systems
Becton Dickinson and Company

12/19/2000
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2001

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

Re: K003461
Trade Name: BD Vacutainer™ Brand Passive Shielding Blood Collection Needle
Regulatory Class: II
Product Code: FMI
Dated: October 27, 2000
Received: November 7, 2000

Dear Ms. Bosshardt:

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.

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) 594-4692. 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 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K003461

Device Name: BD Vacutainer™ Passive Shielding Blood Collection Needle

Indications for Use:

The BD Vacutainer™ Passive Shielding Blood Collection Needle is a sterile, multiple-sample, single-use device intended for venous blood collection. The needle is designed with a passive safety shielding feature and integrated needle holder to aid in the prevention of needle stick injury from both cannula needlepoints. With this passive device, the user automatically activates the safety-shielding feature upon full insertion of the first collection tube. Upon withdrawal of the needle from the venous puncture site no manual manipulation is required to fully activate the safety shield over the cannula. The passive safety shielding mechanism with passive activation has the potential to result in virtually 100% utilization of the safety feature leading to significant reduction in accidental needle stick injury. Passive shielding of the needle cannula upon withdrawal also minimizes the risk of blood splatter.

(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)

Vicki Hilliard for Pat Cucenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003461