OCT 28 1998

K982541

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: Andrea Hroncich
  Regulatory Affairs Coordinator
  Telephone no.: 201-847-6173
  Fax No. 201-847-4858
- Date of Summary: July 16, 1998

Device

- Trade Name: VACUTAINER® Brand ECLIPSE™ Blood Collection Needle
- Classification Name: Blood Specimen Collection Device
- 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 ECLIPSE™ Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.

- Intended Use:

  VACUTAINER® Brand ECLIPSE™ Blood Collection Needle is designed for use with VACUTAINER® Brand Blood Collection Needle Holders in performing venipuncture to obtain blood samples. After venipuncture, the safety shield is activated with thumb pressure. The hinged safety shield pivots up and over the needle, locking into place. In the activated position, the safety shield protects against accidental needle stick during normal handling and disposal.

- Synopsis of Test Methods and Results

  The VACUTAINER® Brand ECLIPSE™ Blood Collection Needle will be made using components that are identical to the conventional VACUTAINER® Brand Blood Collection Needle and function in blood collection is inherently equivalent. It is similar to the VACUTAINER® Brand Safety Blood Collection Assembly in that it has an attached safety shield that can be conveniently activated by the user after phlebotomy to provide protection from accidental needle stick injury. Mechanical Testing was used to confirm acceptable forces to activate the safety shielding including lock engagement and to evaluate conditions and forces under which the safety mechanism can be defeated. Simulated Use Testing by a panel of twenty healthcare professionals was used to confirm reliable shield activation in a blood drawing environment, to observe blood splatter, and to evaluate ease of activation. Other considerations such as technique, right/left handedness, and single-handed operation were also observed. Based on the above, the device is believed to provide performance in blood collection equivalent to the predicate

conventional blood collection needle and to provide a convenient and effective cannula shielding.

- Substantial Equivalence

  Based on comparison of the device features, materials, and intended use, the VACUTAINER® Brand ECLIPSE™ Blood Collection Needle can be shown to be substantially equivalent to the commercially available predicate devices identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER® Systems	VACUTAINER® Brand Blood Collection Needle	N/A	Pre-amendment
Becton Dickinson VACUTAINER® Systems	VACUTAINER® Brand Safety Blood Collection Assembly	K972404	July 22, 1997.

Andrea Hroncich

Andrea Hroncich
Regulatory Affairs Coordinator
Regulatory Affairs Department

7/20/98
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Ms. Andrea Hroncich
Regulatory Affairs Associate
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

Re: K982541
Trade Name: VACUTAINER® Brand Eclipse™ Blood Collection Needle, Models
Regulatory Class: II
Product Code: FMI
Dated: September 18, 1998
Received: September 21, 1998

Dear Ms. Hroncich:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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,

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

Enclosure

G. INDICATIONS FOR USE

510(k) Number (if known): K982541

Device Name: VACUTAINER® Brand ECLIPSE™ Blood Collection Needle

Indications for Use:

The VACUTAINER® Brand ECLIPSE™ Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.

(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 Dental, Infection Control, and General Hospital Devices

510(k) Number K982541