K972404

JUL 22 1997

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BECTON DICKINSON

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

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR 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.: 201 - 847 - 6280
  Facsimile no.: 201 - 847 - 4858
- **Date of Summary:** June 20, 1997

Device Name:

- **Trade Name:** VACUTAINER® Brand Safety Blood Collection Assembly
  Pre-attached SafetyGlide™ Needle and Direct Draw Adapter
- **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

- **Device Description**

The VACUTAINER® Brand Safety Blood Collection Assembly is a configuration of the commercially available BDD SafetyGlide™ Needle pre-attached to a VACUTAINER® Direct Draw Adapter (Blood Collection Holder assembly). The VACUTAINER® Brand Safety Blood Collection Assembly is

intended to be marketed as a sterile, multi-sample, single use device.

- **Intended Use**

The VACUTAINER® Brand Safety Blood Collection Assembly is intended to provide a pre-assembled Direct Draw Adapter/safety needle combination for venipuncture to obtain blood samples. The VACUTAINER® Brand Safety Blood Collection Assembly contains a sliding shield that covers the needle point after use. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal.

- **Synopsis of Test Methods and Results**

The original SafetyGlide™ Needle 510(k) premarket notification K951254 described bench and simulated use testing to support the functional performance and a decision of substantial equivalence. The bench testing which compared the SafetyGlide™ Needle to two commercially available devices included force to activate; hub/arm separation force, safety barrier penetration resistance and reset force. The results demonstrated equivalent or improved performance of the SafetyGlide™ Needle force to activate, hub/arm separation force, safety barrier penetration resistance and reset force. Further, the SafetyGlide™ Needle could not be deactivated.

VACUTAINER Systems, in accordance with the Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions For Medical Devices with Sharps Injury Prevention Features, conducted a Simulated Use Study. The Simulated Use Study was designed to evaluate successful shield activation in a blood drawing environment, observe blood splatter and to evaluate Ease of Activation. The investigators were also requested to document any modification to the current venipuncture technique, observe left/right handed use and single handed use.

A total of 500 VACUTAINER Safety Blood Collection Assembly devices were tested. Results of the study demonstrated successful shield activation for all 500 devices, a 100% success rate with a 0.7% Upper 95% Confidence Limit and a 1.1% Upper 99% Confidence Limit. (The confidence limits is based on the table included in the Supplementary Guidance). Over 90% of the investigators reported "As Expected" Ease of Use with the remaining investigators approximately equally divided in regards to "Easier Than Expected Activation" or "Harder than Expected Activation". Blood Splatter was observed in some instances of use. The Package labeling instructions for use includes handling recommendations intended to reduce the risk of exposure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1997

John A. Schalago
Regulatory Affairs Specialist
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K972404
VACUTAINER® Brand Safety Blood Collection Assembly
Regulatory Class: II
Product Code: KJA
Dated: June 25, 1997
Received: June 26, 1997

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 requirement, 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® Brand Safety Blood Collection Assembly

Indications for Use:

The VACUTAINER® Brand Safety Blood Collection Assembly is intended to provide a pre-assembled Direct Draw Adapter/safety needle combination for venipuncture to obtain blood samples. The VACUTAINER® Brand Safety Blood Collection Assembly contains a sliding shield that covers the needle point after use. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974404

(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)