
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: Keith M. Smith
Senior Regulatory Affairs Specialist
Telephone no.: 201-847-6280
Fax No. 201-847-4858
- Date of Summary: August 14, 1998

Device

- Trade Name: VACUTAINER® Brand Blood Collection Syringe
- 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 VACUTAINER® Brand Blood Collection Syringe is a sterile, single use device designed to collect whole blood specimens for diagnostic testing. The syringe contains dry calcium-balanced lithium heparin (approximately 50 IU per mL of whole blood) derived from porcine intestinal mucosa, as the anticoagulant. Calcium chloride has been added to the formulation to provide a calcium-balanced lithium heparin solution, specifically allowing the measurement of ionized calcium and magnesium. The calcium chloride solution binds to the heparin prior to blood collection allowing electrolytes such as ionized calcium and magnesium in the blood to be measured without interference from the heparin (calcium-balanced).

➤ VACUTAINER Brand A-LINE Kit

Contains a specifically designed syringe only for aspiration of blood samples from arterial lines.

➤ VACUTAINER Brand PRESET™ Kit

Contains a specifically designed syringe (may include needle) that can be preset to a desired volume, but permits aspiration when necessary. Includes a venting system that expels residual air through the self-venting membrane (as blood fills the syringe), which ensures rapid filling.

➤ VACUTAINER Brand DRIHEP® PLUS Kit

Contains a specifically designed syringe (may include needle) with a self-venting membrane, (which seals automatically upon blood contact), and low plunger resistance which permits preset, aspiration, and natural fill sampling. Plunger auto-stop avoids overflow and leakage.

Please Note:

The needle component may be one of two configurations. The needle may be a single lumen hypodermic needle or a SafetyGlide™ Needle, a single lumen hypodermic needle with a hinge safety mechanism. The single lumen hypodermic needle is a pre-amendment device for Becton Dickinson and the SafetyGlide™ Needle was cleared on 10/10/95 via 510(k) K951254.

- Intended Use

The VACUTAINER® Brand Blood Collection Syringe is intended to collect whole blood specimens for diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium and magnesium), metabolites, co-oximetry, and other tests.

- Synopsis of Performance Study Results

Three separate performance studies (anticoagulant & hemolysis, analytical, and clinical) were done to show the performance and equivalence of the principal device with the new calcium-balanced lithium heparin anticoagulant to the predicate devices currently marketed in the United States.

The VACUTAINER® Blood Collection Syringes are substantially equivalent to the performance of the currently marketed predicate devices as presented in this submission. All results from the three studies show equivalence between the principal device and the predicate device. Therefore, the performance of the VACUTAINER Blood Collection Syringes are substantially equivalent to the predicate devices.

III. Predicate Device Summary Table

<p>• Substantial Equivalence</p> <p>Based on comparison of the device features, materials, intended use and performance, the VACUTAINER® Blood Collection Syringe 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 date are also identified in the table below.</p>			
Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson Division	Becton Dickinson Division Arterial Blood Gas Syringe	N/A	Exempt from premarket notification
RADIOMETER AMERICA INC.	Smooth E™ Arterial Blood Sampler	K896514	unknown
CHIRON/Diagnostics RapidLyte™ Arterial Blood Sampler	VACUTAINER Brand Safety Blood Collection Assembly	K875117	2/29/88



 Keith M. Smith
 Senior Regulatory Affairs Specialist
 Becton Dickinson VACUTAINER Systems
 Becton Dickinson and Company

8/14/98

 Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Keith M. Smith
Senior Regulatory Affairs Specialist
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

Re: K982922
VACUTAINER® Brand Blood Collection Syringes
Regulatory Class: II
Product Code: JKA
Dated: August 14, 1998
Received: August 19, 1998

Dear Mr. Smith:

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 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.

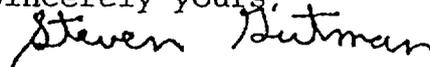
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K982922

Device Name: VACUTAINER® Brand Blood Collection Syringe

Indications for Use:

The VACUTAINER Brand Blood Collection Syringe is intended to collect whole blood specimens for diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium and magnesium), metabolites, co-oximetry, and other tests.

(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)

K982922 (Optional format 1-2-96)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982922