

FEB 4 1998

K980098

Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885
(201) 847-4500

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
Becton Drive
Franklin Lakes, NJ 07417-1885
- **Registration Number:** 2243072
- **Contact Person:** John Schalago
Regulatory Affairs Specialist
Telephone no.: 201-847-6173
Fax No. 201-847-4858
- **Date of Summary:** January 8, 1998

DEVICE

- **Trade Name:** VACUTAINER® Brand Pronto™ Needle Holder
- **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 Pronto™ Needle Holder is a non-sterile, reusable device designed to attach and hold a VACUTAINER® Brand needle or VACUTAINER® Blood Collection set during venipuncture. The holder has a quick release feature which allows the contaminated needle to be disengaged with a simple one handed push-button technique.
- **Intended Use:**
The VACUTAINER® Brand Pronto™ Needle Holder is a non-sterile, reusable device designed to attach and hold a VACUTAINER® Brand needle or VACUTAINER® Blood Collection Set during venipuncture. The holder has a quick release feature which allows the contaminated needle to be disengaged with a simple one handed push-button technique.
- **Synopsis of Test Methods and Results**
In accordance with 21 CFR § 820.30 Design Verification requirements, mechanical testing was conducted to confirm product performance for three key attributes: overtorque (the torque required to activate the release mechanism prematurely), activation force (the force necessary to activate the mechanism to release the needle after venipuncture), and spinout (security of needle after insertion). A total of 30 holders were tested according to established BDVS procedures for these attributes, with results indicating acceptable product performance.
- **Substantial Equivalence**
Based on comparison of the device features, the VACUTAINER® Brand Pronto™ Needle Holder can be shown to be substantially equivalent to the commercially available predicate devices, the Bio-Plexus Drop-It™ Needle Holder and SAGE® Needle Holder. The predicate devices, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
SAGE PRODUCTS, INC.	AUTODROP®	N/A	N/A
Bio-Plexus	Drop-It™ Needle Holder	K963748	6/6/97

John Schalago
John Schalago
Regulatory Affairs Specialist
Regulatory Affairs Department

1-8-98
Date



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

John Schalago
Regulatory Affairs Specialist
Becton Dickinson
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

FEB - 5 1998

Re: K980098
Vacutainer® Brand Pronto™ Needle Holder
Regulatory Class: II
Product Code: JKA
Dated: January 9, 1998
Received: January 12, 1998

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 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.

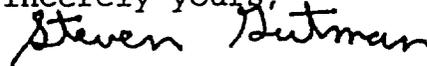
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(K) NUMBER (IF KNOWN): _____

DEVICE NAME: VACUTAINER® BRAND PRONTO™ NEEDLE HOLDER

INDICATIONS FOR USE:

The VACUTAINER® Brand Pronto™ Needle Holder is a non-sterile, reusable device designed to attach and hold a VACUTAINER® Brand needle or VACUTAINER® Blood Collection Set during venipuncture.

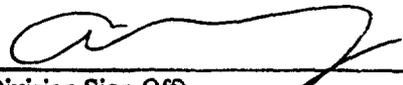
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 6480098