K012043

SEP 2 4 2001

June 27, 2001

510(k) Summary

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICES:

Trade Name:	Vacuette® EDTA K2 Gel Tubes
Common Names/Descriptions:	Evacuated Blood Collection System
Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICE:

Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube (K972075)

DEVICE DESCRIPTION:

INTENDED USE: The **VACUETTE®** EDTA K2 Gel tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume, and a gel barrier material.

PRODUCT DESCRIPTION: The **VACUETTE®** EDTA K2 Gel Tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR – Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

SUBSTANTIAL EQUIVALENCE:

The VACUETTE® EDTA K2 Gel Tube and the Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube are substantially equivalent in intended use, design and composition.

Studies were conducted to evaluate the use of the Greiner VACUETTE® EDTA K2 Gel Tubes. The objective of the studies was to demonstrate substantial equivalence to the Becton Dickinson (BD) Vacutainer® Brand PPT™ Plasma Preparation Tube when samples from these tubes are used in PCR assays.

The substantial equivalence studies included:

- Limited validation testing on the HIV and HCV PCR assays using WHO standards at the lower detection limits; comparison of HIV and HCV lower detection limits using both types of tubes;
- Comparison of HIV and HCV recovery using both types of tubes;
- Equivalency studies of Greiner and BD tubes with regard to results of HIV and HCV PCR testing;
- Evaluation of effects of delay in separation of plasma and blood cells on HIV and HCV results using both types of tubes;
- Determination of equivalency of HIV and HCV results from fresh and once frozen samples collected in the two tube types;
- Determination of equivalency of HIV and HCV results from fresh and multiple freeze/thaw samples using both types of tubes.

The conclusions from the study were:

- Both tubes demonstrated similar sensitivity and recovery at the lower detection limits for both HIV and HCV quantitation;
- Both tubes demonstrated substantially equivalent results in HIV and HCV quantitation;
- No effect was seen when plasma collected from the Greiner tube was separated from blood cells within 24 hours for HIV or HCV;
- There was no difference in HIV or HCV results within or between the two tube types for fresh versus once frozen samples or when plasma samples were exposed to 5 freeze/thaw cycles for HIV or 1 freeze/thaw cycle for HCV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Greiner Vacuette North America, Inc.
c/o Ms. Judi Smith
Sienna Partners, L.L.C.
P.O. Box 103
Baldwin, MD 21013

SEP 2 4 2001

Re: k012043
Trade/Device Name: Vacuette® EDTA K2 Gel Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 28, 2001
Received: August 30, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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,

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): K012043

Device Name: **VACUETTE®** EDTA K2 Gel Tubes

Indications For Use: The **VACUETTE®** EDTA K2 Gel tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume, and a gel barrier material. The **VACUETTE®** EDTA K2 Gel tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR – Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012043

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)