K011699

JUN 2 8 2001

May 31, 2001

510(K) SUMMARY

Greiner VACUETTE® Evacuated Blood Collection Tubes with Sodium Heparin

Greiner VACUETTE® North America, Inc.
P.O Box 1026
Monroe, NC 28111

For information regarding this 510(k) Summary, please contact Greiner VACUETTE® North America, Douglas L. Harris.

Device Names:

Proprietary Name: **VACUETTE®** Evacuated Blood Collection Tube with Sodium Heparin

Common Name: Blood Collection Tube with Sodium Heparin

Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

Device Description:

VACUETTE® Tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. The **VACUETTE®** tube with sodium heparin may be used to collect a whole blood/plasma sample. The tube is composed of clear plastic. The cap is made of plastic and rubber. The tube size is 13 x 75 mm. The tube is equipped with a vacuum tube holder to assist in positioning the product when obtaining blood samples. The vacuum tube holder is composed of plastic.

Intended Use:

The Greiner **VACUETTE®** blood collection tube with sodium heparin additive is an evacuated blood collection device that is used for the collection of venous blood. The **VACUETTE®** Tube is used to collect, transport and process blood for testing plasma or whole blood in the clinical laboratory.

Substantial Equivalence:

The Greiner **VACUETTE®** tube with sodium heparin has been found to be substantially equivalent to the Greiner **VACUETTE®** tube with lithium heparin (K# 960857). Both blood collection tubes have the same intended use and contain the same tube material and stopper material. The tubes have different additives. The predicate device, Greiner **VACUETTE®** plasma tube with lithium heparin, contains lithium heparin as the anticoagulant. The Greiner **VACUETTE®** plasma tube with sodium heparin contains sodium heparin as the anticoagulant.

A study was conducted on blood collected from 40 donors into each type of tube. Test results of 27 analytes commonly tested in plasma showed equivalent performance of the two anticoagulants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Greiner Bio-One Vacuette North America
c/o Ms. Judith J. Smith
Principal
Suenna Partners, L.L.C.
P.O. Box 103
Baldwin, MD 21013

JUN 2 8 2001

Re: 510(k) Number: K011699
Trade/Device Name: Vacuette® Blood Collection Tubes with Sodium Heparin
Regulation Number: 862.1675
Regulatory Class: II
Product Code: JKA
Dated: May 31, 2001
Received: June 1, 2001

Dear Ms. 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 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) 594-4588. 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 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): K010699

Device Name: VACUETTE® Blood Collection Tubes with sodium heparin

Indications For Use:

VACUETTE® tubes with sodium heparin are used to collect, transport and process blood for testing plasma or whole blood in the clinical laboratory.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011699

(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)