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November 27, 2002

510(K) SUMMARY

Greiner VACUETTE® Trace Elements Tubes

K023971

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®** Trace Elements Tubes

Common Name: Blood Collection Tubes

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®** Trace Elements tube with sodium heparin may be used to collect a whole blood/plasma sample. The **VACUETTE®** Trace Elements tube with no additive may be used to collect a serum sample. The tubes are composed of clear plastic. The caps are royal blue and made of plastic and rubber; the inner cap rings are black and made of plastic. The tubes' size is 13 x 75 mm, 6mL draw. The tubes are 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:

VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood. The Greiner **VACUETTE®** Trace Elements tubes with sodium heparin or no additive are used to collect, transport and process blood for testing plasma, serum, or whole blood for trace elements in the clinical laboratory.

Substantial Equivalence:

The Greiner **VACUETTE®** Trace Elements tubes are substantially equivalent to the Becton Dickinson **Vacutainer®** Trace Elements tube with sodium heparin (pre-amendment). The blood collection tubes have the same intended use and contain the same tube material and stopper material; the **VACUETTE®** Trace Elements tube containing sodium heparin contains the same anticoagulant.

Two studies were conducted on the tubes – testing for presence of trace elements in the tubes using deionized water and comparison testing using blood collected from 40 blood donors. Test results for trace elements to be claimed showed no background presence of trace elements in the tubes and equivalent performance with blood samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JAN 2 7 2003

Re: k023971
Trade/Device Name: Greiner VACUETTE® Trace Elements Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: November 27, 2002
Received: November 29, 2002

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023971

Device Name: Greiner VACUETTE® Trace Elements Evacuated Blood Collection Tubes with sodium heparin or no additive

Indications For Use:

Greiner VACUETTE® Trace Elements Evacuated Blood Collection Tubes with sodium heparin or no additive are used to collect, transport and process blood for testing plasma, serum, or whole blood for trace elements in the clinical laboratory.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023971

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

(Optional Format 1-2-96)