

K103041

NOV - 9 2010

November 8, 2010

510(k) SUMMARY

CONTACT:

Manfred Abel
Greiner Bio-One North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICE:

Trade Name: Greiner VACUETTE® Blood Collection Tube with Lithium Heparin and Gel
Common Names/Descriptions: Evacuated Blood Collection System
Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICE:

Greiner VACUETTE® Blood Collection Tube with Lithium Heparin and Gel

DEVICE DESCRIPTION:

INTENDED USE:

VACUETTE® Blood Collection Tubes with Lithium Heparin and Gel Separator are used to collect, transport and process blood for testing plasma in the clinical laboratory.

DESCRIPTION:

VACUETTE® Evacuated Blood Collection Tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with color coded VACUETTE® Safety Caps (green for heparin tubes). The tubes, additive concentrations, volumes of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance to the requirements and recommendations of the international standards ISO 6710 "Single use containers for venous blood specimen collection" and the Clinical and Laboratory Standards Institute's Approved Standards (CLSI).

VACUETTE® Evacuated Blood Collection Tubes with Lithium Heparin and Gel contain a barrier gel in the tube. The specific gravity of this material lies between the blood cells and plasma. During centrifugation the gel barrier moves upward, where it forms a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, which eliminates the need for transfer to another container.

The changes for the VACUETTE® Evacuated Blood Collection Tube with Lithium Heparin and Gel are in the Instructions for Use (IFU):

- Recommended g-force (relative centrifugal force, rcf) change from 2200 g to a range of 1800 – 2200 g.
- Recommended tube spin time change from 15 minutes to a range of 10 – 15 minutes.

SUBSTANTIAL EQUIVALENCE:

The Greiner **VACUETTE**[®] Blood Collection Tube with Lithium Heparin and Gel described in this submission is substantially equivalent to the predicate device in intended use, design, or composition of the tube. Verification studies were performed to demonstrate that the lower centrifugation speed and time did not affect laboratory results compared to the current centrifugation speed and time. The following table summarizes the validation and verification studies, the acceptance criteria, and the results.

Summary of the Verification and Validation Activity

Parameters	Risks	Tests Performed	Pre-Determined Acceptance Criteria	Test Results
Modification of the centrifuge g force and time (From 15 minutes at 2200 g to 10 minutes at 1800 g)	1. Incomplete gel barrier formation causing incomplete separation of plasma and red blood cells	Method comparison study between the current centrifuge speed and time versus the modified centrifuge speed and time from 40 patients (51 analytes tested)	Visually inspected all of the tubes after centrifugation and before starting analysis: 99% of the time all gel barriers must be properly formed and stable	Passed: All met acceptance criteria (100% of tubes formed stable gel barriers)
	2. Inaccurate results of the analytes tested from the plasma	Method comparison study between the current centrifuge speed and time versus the modified centrifuge speed and time from 40 patients (51 analytes tested)	All test results must yield: 1. Deming slope of 1.0 ± 0.1 2. No statistically significant difference between results: using Deming Method, the 95% confidence intervals include the ideal values (i.e. 0.00 in constant bias or 1.00 in proportional bias)	Passed: All met acceptance criteria

The analysis of the data from this study demonstrated that the current modified centrifugation conditions for the **VACUETTE**[®] Evacuated Blood Collection System are equivalent and can be used for a broad range of clinical chemistry and immunology tests.



Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Greiner Bio-One North America, Inc.
c/o Judi Smith, LLC, Principal
PO Box 103
Baldwin, MD 21013 USA

Re: k103041
Trade Name: Greiner VACUETTE® Blood Collection Tube with Lithium Heparin
and Gel
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Codes: JKA
Dated: October 5, 2010
Received: October 14, 2010

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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.

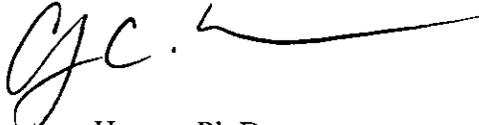
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CHC', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

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510(k) Number (if known): k103041

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Indication For Use:

VACUETTE[®] Blood Collection Tubes with Lithium Heparin and Gel Separator are used to collect, transport and process blood for testing plasma in the clinical laboratory.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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