DEC 28 1998

K983952

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner Meditech, Inc. ("Greiner") is submitting a labeling change to its already approved VACUETTE® blood collection tube with clot activator and gel separator (K960858). The Greiner VACUETTE® blood collection tube with clot activator and gel separator is an evacuated blood collection device containing a clot activator and an inert polymeric barrier material. The product is intended for use in collecting, transporting, storing and processing blood serum from cellular components of blood. The labeling change is to exclude the existing contraindication on labeling of the VACUETTE® Blood Collection tube with clot activator and gel separator for use of the tube in therapeutic drug monitoring, and to include on the labeling a statement that the tubes are suitable for such use.

Greiner is claiming substantial equivalence to its previously cleared VACUETTE® blood collection tube with clot activator and gel separator (K960858) and to Becton Dickinson VACUTAINER® Brand plain glass blood collection tubes. The modified blood collection tubes still will have the same basic intended use as the cleared VACUETTE® tube, with the additional use for therapeutic drug monitoring. The plastic tube material, clot activator and gel separator material will remain the same as in the cleared VACUETTE® tube (K960858). Clinical tests show that there is no significant clinical difference between Greiner VACUETTE® blood collection tubes with clot activator and gel separator and Becton Dickinson plain glass blood collection tubes. Clinical tests compared Greiner VACUETTE® blood collection tubes with clot activator and no gel separator, and VACUETTE® blood collection tubes with clot activator and gel separator to Becton Dickinson VACUTAINER® Brand plain glass blood collection tubes. No clinically significant difference was noted in these comparison studies.

Greiner's 510(k) has been submitted on November 2, 1998 by Doug Harris, Managing Director, Greiner Meditech, Inc., 260 Gateway Drive, Suite 17A, Bel Air, MD 21014 (410) 836-8228.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 28 1998

Douglas L. Harris
Managing Director
Greiner Meditech, Inc.
P.O. Box 943
Bel Air, MD 21014

Re: K983952
Trade Name: VACUETTE® Blood Collection Tube w/ Clot Activator and Gel Separator
Regulatory Class: II
Product Code: JKA
Dated: November 5, 1998
Received: November 5, 1998

Dear Mr. Harris:

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 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). 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.

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/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

greiner meditech
P.O. Box 943
Bel Air, Maryland 21014

510(k) Number (if known): K983952

Device Name: VACUETTE® Blood Collection Tube with Clot Activator and Gel Separator

Indications For Use: To collect, transport, store and process blood for testing serum in the clinical laboratory. In addition, tubes are suitable for therapeutic drug monitoring.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983952

Prescription Use X

Over-the-Counter Use ____