OCT 19 1998

K982999

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner Meditech, Inc. („Greiner") is submitting a 510(k) premarket notification for its Greiner MiniCollect® EDTA tube with EDTA K_3 for capillary blood collection. The Greiner MiniCollect® EDTA K_3 tube is a non-sterile, non-evacuated blood collection device containing EDTA K_3 anticoagulant additive, and is intended for use in evaluations of capillary blood specimens.

Greiner is claiming substantial equivalence to Becton Dickinson's Microtainer® EDTA K_2 tube (K940905). Both blood collection tubes have the same intended use and are made out of the same material, polypropylene plastic. The Becton Dickinson Microtainer® EDTA tube uses EDTA K_2 as an additive, while the Greiner MiniCollect® EDTA tube uses EDTA K_3 as an additive. The Greiner MiniCollect® tube cap is made from rubber and has "cross-cuts" to allow for direct collection into and sampling from the tube without having to remove the cap. The Becton Dickinson Microtainer® Brand EDTA tube caps are made of polyethylene. The equivalency of assay results for both tubes was evaluated by testing paired samples collected in Greiner MiniCollect® EDTA K_3 tubes and Becton Dickinson Microtainer® Brand EDTA K_2 tubes. Test results from paired samples for 15 hematology parameters and lead tests were evaluated and good correlation was observed.

Greiner's 510(k) has been submitted on August 27, 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

OCT 16 1998

Douglas L. Harris
Managing Director
Greiner Meditech, Inc.
260 Gateway Drive, Suite 17A
P.O. Box 943
Bel Air, Maryland 21014

Re: K982999
MiniCollect® EDTA K_3 Blood Collection Tube
Regulatory Class: II
Product Code: JKA
Dated: August 27, 1998
Received: August 27, 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 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K982999

Device Name: MiniCollect® EDTA K_3 Blood Collection Tube

Indications for Use: To collect, transport, store, and evaluate capillary blood specimens for hematology and lead tests.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982999

Prescription Use ___X___ Over-The-Counter Use _____