K971220 JUN - 4 1997

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner America, Inc. ("Greiner") is submitting a 510(k) premarket notification for its Greiner Vacuette® eurythrocyte sedimentation rate ("ESR") blood collection tube with citrate solution. The Greiner Vacuette® ESR blood collection tube with citrate solution is an evacuated blood collection device intended for use in evaluations of blood sedimentation rate.

Greiner is claiming substantial equivalence to Becton Dickinson's Vacutainer® brand citrate ESR tube. Both blood collection tubes have the same intended use and contain the same stopper material and additive. The tube material for both the Greiner product and for the Becton Dickinson product is glass. The equivalency of assay results of the two tubes was evaluated by testing paired samples collected in Greiner Vacuette® tubes and Becton Dickinson Vacutainer® tubes. Test results from paired samples for eurythrocyte sedimentation rate were evaluated and good correlation was observed.

Greiner's 510(k) has been submitted on April 1, 1997, by Ed Maier, Managing Director, Greiner America, Inc., P.O. Box 953279, Lake Mary, Florida 32795-3279 (407/333-2800).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 4 1997

Ed Maier
Managing Director
Greiner America, Inc.
P.O. Box 953279
Lake Mary, Florida 32795-3279

Re: K971220
Greiner Vacuette Blood Collection Tube
Regulatory Class: I & II
Product Code: JKA, GIM, GHC
Dated: May 16, 1997
Received: May 20, 1997

Dear Mr. Maier:

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 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.

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

Device Name: Vacuette® ESR blood collection tube with citrate solution

Indication for Use: To evaluate blood sedimentation rates

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510(k) K971220

Prescription Use X

Over-The-Counter-Use ____

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