

K930454

AUG 5 1988

**510(k) Summary of Safety and Efficacy Upon Which  
Substantial Equivalence is Based**

**Boehringer Mannheim CoaguChek® System**

The Boehringer Mannheim CoaguChek System is substantially equivalent to the Coumatrak Test System sold by DuPont Company and manufactured by Biotrak, Inc. Both systems are intended for the quantitative measurement of prothrombin time in fresh whole blood. A correlation coefficient of 0.944 was achieved. With the CoaguChek System a mean level of 12.6 seconds yielded a standard deviation of 0.35 seconds and a coefficient of variation of 2.8 %. A mean level of 22.8 seconds yielded a standard deviation of 1.01 seconds and a coefficient of variation of 4.4%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 5 1993

Mr. John D. Stevens, R.A.C.  
Boehringer Mannheim Corp.  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850  
Re: K930454  
Product: Boehringer  
Mannheim  
Coaguchek® System  
Dated: January 15, 1993  
Received: January 27, 1993  
Regulatory Class: II

Dear Mr. Stevens:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

*Steven Gutman*

Steven I. Gutman, M.D., MBA  
Acting Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health