DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 9 1998

Mr. Richard Naples
Director, Regulatory Affairs
Boehringer Mannheim
9115 Hague Road
Indianapolis, Indiana 46250

RE: K974569
Trade Name: CoaguChek System (Professional Use) and CoaguChek PST (Patient Self Testing)
Regulatory Class: II
Product Code: JPA
Dated: December 5, 1997
Received: December 8, 1997

Dear Mr. Naples:

We have reviewed your Section 510(k) notification of intent to market the CoaguChek System (Professional Use) and the CoaguChek PST (Patient Self Testing) devices under a single 510(k) number as referenced above and we have determined that these two devices are 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). Please note that the consolidation of these two devices under a single 510(k) number, K974569, does not change the fact that there are two separate and different intended uses for these devices, one for professional use and one for home use by prescription, and two different sets of quality control recommendations for the two devices. You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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), these devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597,or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

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

Enclosure

510(k) Number (if known): K974569

Device Names: CoaguChek System for Professional Use and the CoaguChek System for Patient Self Testing

Indications For Use:

The CoaguChek System for professional use is intended for quantitative prothrombin time (PT) testing in fresh capillary or venous whole blood by professional health care providers. The CoaguChek System for Patient Self Testing is intended for the quantitative prothrombin time (PT) testing in fresh capillary blood by selected and suitably trained patients or their caregivers on the prescription of the treating physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven Butman

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974569

Prescription Use_X___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)