

AUG 12 1997

510(k) Summary

K 972235

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers, RAC

Date Prepared: June 13, 1997

2) Device name Proprietary name: PreciControl Tumor Marker

Common name: Quality Control Material

Classification name: Multi-Analyte Control, all kinds, (assayed + unassayed)

3) Predicate device We claim substantial equivalence to Bio-Rad Lyphocheck Immunoassay Plus Control.

4) Device Description PreciControl Tumor Marker contains lyophilized control serum based on human serum. The concentrations are in two clinically relevant ranges. The controls are used for monitoring the accuracy and precision of Elecsys immunoassays.

Continued on next page

5) Intended use PreciControl Tumor Marker is used for quality control of Elecsys immunoassays using the Elecsys immunoassay systems.

6) Comparison to predicate device The Boehringer Mannheim PreciControl Tumor Marker is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Bio-Rad Lyphocheck Immunoassay Plus Control.

The intended use of both the PreciControl Tumor Marker and the predicate device are the same in that they are intended to estimate test precision and detect systematic analytical deviations on automated immunoassay systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. LeeAnn Chambers, RAC
Program Manager, Regulatory Affairs
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46250

AUG 12 1997

Re: K972235
Trade Name: PreciControl Tumor Marker
Regulatory Class: I
Product Code: JJY
Dated: June 13, 1997
Received: June 16, 1997

Dear Ms. Chambers:

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 (Pre-market 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 requirement, 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 pre-market 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.

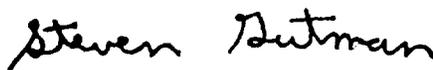
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



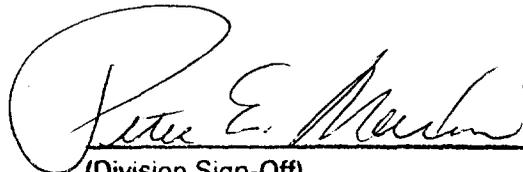
Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972235
Device Name: PreciControl Tumor Marker
Indications for Use:

PreciControl Tumor Marker is used for quality control of Elecsys immunoassays using the Elecsys immunoassay systems (Elecsys 2010, 1010 and others of the Elecsys family of instruments).

PreciControl Tumor Marker contains lyophilized control serum based on human serum. The concentrations are in two clinically relevant ranges. The controls are used for monitoring the accuracy and precision of Elecsys immunoassays.



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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)