

510(k) Summary

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) 576-3723

Contact person: Priscilla A. Hamill

Date prepared: October 1, 1998

2) Device name **Proprietary name:** Boehringer Mannheim Elecsys ® PreciControl Cardiac

Common name: Elecsys ® PreciControl Cardiac

Classification name: Enzyme Controls (assayed and unassayed)

3) Predicate device We claim substantial equivalence to Elecsys ® PreciControl Cardiac (K962575).

4) Device description Boehringer Mannheim Elecsys ® PreciControl Cardiac is a bilevel lyophilized preparation of pooled human sera containing CK-MB (human), Troponin T (human recombinant) and Myoglobin (human) for monitoring the accuracy and precision of Elecsys CK-MB, Troponin T and Myoglobin immunoassays.

Continued on next page

510(k) Summary, Continued

5) Intended use Boehringer Mannheim Elecsys® PreciControl Cardiac is intended for use for quality control of the Elecsys CK-MB, Troponin T (CARDIAC T®), and Myoglobin immunoassays using the Elecsys immunoassay systems.

6) Comparison to the predicate device Boehringer Mannheim Elecsys® PreciControl Cardiac is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the current Elecsys® PreciControl Cardiac controls marketed by Boehringer Mannheim Corporation. These controls were cleared by the FDA based on 510(k) submissions by Boehringer Mannheim. The 510(k) number for the Elecsys® PreciControl Cardiac is K962575.

The intended use of this BM control and the predicate device is the same in that they are intended to be used for the quality control of Elecsys immunoassays for cardiac proteins.

The only significant differences are

- the inclusion of an additional constituent analyte (myoglobin), and
 - the replacement of bovine heart troponin T by human recombinant troponin T.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 9 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Priscilla A. Hamill
• Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K983492
Elecsys® PreciControl Cardiac
Regulatory Class: I
Product Code: JJY
Dated: October 1, 1998
Received: October 5, 1998

Dear Ms. Hamill:

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.

510(k) Number (if known): K 98 3492

Device Name: Boehringer Mannheim Elecsys ® PreciControl Cardiac

Indications for Use: Elecsys ® PreciControl Cardiac is used for quality control of the Elecsys CK-MB, Troponin T (CARDIAC T®) and Myoglobin immunoassays using the Elecsys immunoassay systems.

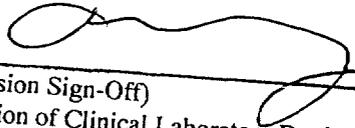
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)

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)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 98 3492

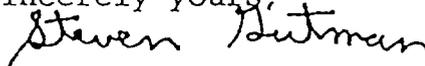
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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