K984372

DEC 14 1998

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.

Submitter name, address, contact

Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 845 - 3723

Contact Person: Priscilla A. Hamill

Date Prepared: December 3, 1998

Device name

Proprietary name: Elecsys CalCheck Troponin T

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

Predicate device

The Boehringer Mannheim Elecsys CalCheck Troponin T is substantially equivalent to the currently marketed Elecsys CalCheck Troponin T.

Device description

The Boehringer Mannheim Elecsys CalCheck Troponin T is manufactured using bovine serum albumin, human recombinant Troponin T, stabilizers, and preservatives. The analyte is appropriately spiked into the CalCheck matrix to the correct CalCheck concentration levels.

Continued on next page

510(k) Summary, Continued

Intended use	The Boehringer Mannheim Elecsys® CalCheck™ Troponin T is used to verify the calibration assignment for the Boehringer Mannheim Elecsys Troponin T assay.
Comparison to predicate device	The Boehringer Mannheim Elecsys® CalCheck™ Troponin T is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® CalCheck™ Troponin T. Both products are intended to be used for the verification of calibration for analytes on the Elecsys immunoassay analyzers.
Performance Characteristics	The Elecsys® CalCheck™ Troponin T was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 1998

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis Indiana 46250-0457

Re: K984372
Trade Name: Elecsys CalCheck Troponin T
Regulatory Class: I
Product Code: JJY
Dated: December 3, 1998
Received: December 7, 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 legally marketed predicate 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.

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/dsma/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

510(k) Number (if known): N/A K984372

Device Name: Boehringer Mannheim Elecsys® CalCheck™ Troponin T

Indications For Use:

Elecsys CalCheck Troponin T calibration verification solutions comprise three levels - low, mid, and high - each with a defined Troponin T concentration. The low solution concentration is near the lower detection limit of the assay. The middle solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys CalCheck Troponin T is intended for use in periodic verification of the calibration of the Elecsys Troponin T assay.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984372