

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 Rd
Indianapolis, IN 46250
(317) 845-3723

Contact person: Priscilla A. Hamill

Date prepared: November 13, 1998

Device name **Proprietary name:** Elecsys ® Troponin T STAT Test
Common name: Troponin T Test
Classification name: Immunoassay method, troponin subunit

Predicate device We claim substantial equivalence to the currently marketed Boehringer Mannheim Elecsys ® Troponin T test.

Device description The Boehringer Mannheim Elecsys ® Troponin T STAT test is based on a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined via a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

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Intended use For the in vitro quantitative determination of troponin T in human serum and plasma

Indications for use The specificity and sensitivity of troponin T measurements aid in both the early and late diagnosis of AMI. Troponin T elevations have also been measured in patients with the clinical diagnosis of unstable angina due to the sensitivity of troponin T for detecting minor myocardial damage.

Comparison to the predicate device The modified Boehringer Mannheim Elecsys Troponin T test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the Boehringer Mannheim Elecsys Troponin T test cleared by FDA in K961500.

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Similarities The following table compares the modified Boehringer Mannheim Elecsys Troponin T test with the predicate device. Specific data on the performance of the test have been incorporated into the draft labeling in Attachment 5. Labeling for the predicate device is provided in Attachment 6.

Similarities

| Feature | Modified device | Predicate device |
|--------------------------|---|--|
| Intended use | For the in vitro quantitative determination of troponin T in human serum and plasma | For the in vitro quantitative determination of troponin T in human serum and plasma |
| Indications for use | An important component in the diagnosis of myocardial ischemia, eg. AMI and myocarditis, as well as in monitoring the course of unstable angina pectoris and assessing the associated risk. | An aid in both the early and late diagnosis of AMI. Troponin T elevations have also been measured in patients with the clinical diagnosis of unstable angina due to the sensitivity of troponin T for detecting minor myocardial damage. |
| Sample type | Human serum, plasma | Human serum, plasma |
| Assay reaction principle | Two step sandwich immunoassay using streptavidin particle and biotinylated antibody capture system | Two step sandwich immunoassay using streptavidin particle and biotinylated antibody capture system |
| Antibody | Mouse monoclonal (no change in antibody) | Mouse monoclonal |
| Measurement approach | Electrochemiluminescence | Electrochemiluminescence |
| Duration of assay | 9 minutes | 9 minutes |

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Differences

Differences: The following differences between the modified Boehringer Mannheim Elecsys Troponin T test and the predicate device are not significant for purposes of determining substantial equivalence.

- Component concentrations have been modified
 - Modified device calibrator contains human recombinant troponin T rather than bovine heart troponin T, used in the predicate device calibrator.
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DEC 8 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Priscilla A. Hamill
Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: K984105

Trade Name: Elecsys® Troponin T Stat Test
Regulatory Class: II
Product Code: MMI
Dated: November 13, 1998
Received: November 17, 1998

Dear Ms. Hamill:

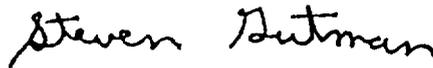
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 984105

Device Name: Boehringer Mannheim ® Elecsys Troponin T STAT

Indications for Use:

Troponin T (TnT) is a component of the contractile apparatus of the striated musculature. Although the function of TnT is the same in all striated muscles, TnT originating exclusively from the myocardium (cardiac TnT, molecular weight 39.7 kD) clearly differs from skeletal muscle TnT. As a result of its high tissue-specificity, cardiac troponin T (cTnT) is a cardiospecific, highly sensitive marker for myocardial damage. In cases of acute myocardial infarction, troponin T levels in serum rise about 3-4 hours after the occurrence of cardiac symptoms and can remain elevated for up to 14 days.

The determination of cTnT in serum is an important component in the diagnosis of myocardial ischemia, e.g. AMI and myocarditis, as well as in monitoring the course of unstable angina pectoris and assessing the associated risk.¹⁻⁶

Comparative studies on 770 patients confirm the prognostic utility of cTnT.⁷ It has also been shown that cTnT-positive patients benefit particularly from antithrombotic therapy strategies (e.g. low molecular weight heparin, BPIIb/IIIa antagonists).^{8,9}

Elevated serum cTnT values are detectable in about 30% of patients suffering from renal failure (e.g. chronic hemodialysis patients). The cTnT detected in these patients is of cardiac origin. It has been demonstrated e.g. with RT-PCR, that cTnT is not expressed in regenerated skeletal musculature of patients with renal failure.^{10,11} Clinical data increasingly demonstrate that such patients have a high risk of subsequently suffering cardiovascular complications.¹²⁻¹⁵

References

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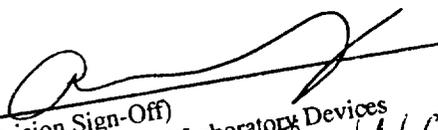
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 KC 98 4105