

K964372

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510(k) Summary CARDIAC T[®] Troponin T Rapid Assay Modification

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
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2) Device name Proprietary name: CARDIAC T[®] Troponin T Rapid Assay

Common name: troponin test

Classification name: Immunoassay method, troponin subunit

3) Predicate device We claim substantial equivalence to the currently marketed CARDIAC T[®] Troponin T Rapid Assay.

4) Device Description The CARDIAC T[®] Troponin T Rapid Assay (2nd generation) test principle is based on the dual monoclonal antibody "sandwich" principle using a poly(streptavidan)-biotin capture system with a gold sol particle label. The test is initiated by the addition of whole blood to the CARDIAC T Rapid Assay, which separates red blood cells from plasma.

5) Intended use The CARDIAC T Rapid Assay is intended for the qualitative determination of cardiac troponin T in anticoagulated venous or arterial whole blood. The measurement of cardiac troponin T has been shown to aid in the diagnosis of acute myocardial infarction (injury).

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510(k) Summary, CARDIAC T[®] Troponin T Rapid Assay Modification, Continued

6) Comparison to predicate device

The Boehringer Mannheim CARDIAC T[®] Troponin T Rapid Assay (2nd generation) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed CARDIAC T[®] Troponin T Rapid Assay.

The following table compares the CARDIAC T[®] Troponin T Rapid Assay (2nd generation) with the predicate device, CARDIAC T[®] Troponin T Rapid Assay. 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	2nd generation Rapid Assay	1st generation Rapid Assay
Intended use	Aid in the diagnosis of acute myocardial infarction (injury)	Same
Sample type	Whole blood containing EDTA or Heparin	Same
Sample volume	130 - 160 μ L	Same
Reaction test principle	Dual monoclonal antibody "sandwich" principle	Same

Differences:

Feature	2nd generation Rapid Assay	1st generation Rapid Assay
antibodies	MAK M11-7 and MAK M-7	MAK 1B10 and MAK M-7
Cut - off	≥ 0.08 ng/mL	≥ 0.20 ng/mL
Read time	15 - 30 minutes	20 - 45 minutes

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**510(k) Summary, CARDIAC T[®] Troponin T Rapid Assay
Modification, Continued**

6) Comparison to predicate device, (cont.) **Performance Characteristics:**

Feature	2nd generation Rapid Assay	1st generation Rapid Assay
Cut-off	≥0.08 ng/mL	≥0.20 ng/mL
Method Comparison	335 individual patient results were compared between the the assays demonstrating agreement in 156 of 179 cases	
Interfering substances	Evaluated for hemolysis, icterus, biotin, Intralipid and 31 common pharmaceutical compounds. No interference at the levels tested	Evaluated for interference from hemolysis, icterus, biotin, Intralipid and 31 common pharmaceutical compounds. No interference at the levels tested