

AUG 23 1996

510(k) Summary**Elecsys® CalCheck™ CK-MB**

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- 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.
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- 1) Submitter name, address, contact** Boehringer Mannheim Corporation
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- Date Prepared: August 12, 1996
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- 2) Device name** Proprietary name: Elecsys CalCheck CK-MB
- Common name: Calibration Verification Material
- Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3) Predicate device** We claim substantial equivalence to the Tosoh Medic AIA-Pack HCG Calibration Verification Test Set, K924862. The intended use for both products is to verify the calibration curve of automated immunoassay analyzers
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- 4) Device Description** The Elecsys CalCheck CK-MB is a three level single analyte set of lyophilized, human based materials. After reconstitution they are assayed in triplicate and the results are compared to the target values.
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- 5) Intended use** Elecsys CalCheck CK-MB is intended for use in the quantitative verification of the calibration curve established by the Elecsys CK-MB reagents and calibrators on Elecsys 1010 or 2010 immunoassay analyzers.

510(k) Summary, Elecsys® CalCheck™ CK-MB, Continued

**6) Comparison
to predicate
device**

The Boehringer Mannheim Elecsys CalCheck CK-MB is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Tosoh Medics AIA-Pack HCG Calibration Verification Test Set, K924862.

The intended use of both the Elecsys CalCheck CK-MB and the predicate device are the same in that they are intended to be used for the calibration verification for their labeled analytes on automated immunoassay analyzers.