

K970452

MAR - 6 1997

## 510(k) Summary

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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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(510) 827 - 8215  
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Contact Person: Patricia M. Klimley

Date Prepared: January 29, 1997

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**2. Device Name** Proprietary name: Elecsys CalCheck CEA  
Common name: Calibration Verification Material  
Classification name: Single (specified) analyte controls (assayed + unassayed)

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**3. Predicate device** The Elecsys® CalCheck™ CEA is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

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**4. Device Description** The Elecsys® CalCheck™ CEA is a three level single analyte set of lyophilized, human based materials. After reconstitution, they are assayed in triplicate and the results compared to the target values.

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## 510(k) Summary, Continued

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**5. Intended use** The Elecsys® CalCheck™ CEA is used to verify the calibration assignment for the Elecsys® CEA assay.

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**6. Comparison to predicate device** The Elecsys® CalCheck™ CEA is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

The following table compares the Boehringer Mannheim Elecsys® CalCheck™ CEA with the predicate device, Elecsys® CalCheck™ TSH. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices is provided in attachment 6.

**Similarities:**

- Configuration: 3 CalCheck levels: low, mid, and high
- Intended use: To verify calibration

**Differences:**

<b>Feature</b>	<b>CalCheck CEA</b>	<b>CalCheck TSH</b>
Matrix type	Human serum	Horse serum
Analyte	CEA	TSH

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## 510(k) Summary, Continued

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6.  
Comparison  
to predicate  
device, (cont.)

**Performance Characteristics:**

- Value assignment and stability
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