

K964829

DEC 16 1996

**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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Fax number: (510) 687-1850  
  
Contact Person: Yvette Lloyd  
  
Date Prepared: December 12, 1996
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- 2. Device Name** Proprietary name: Elecsys CalCheck FSH  
  
Common name: Calibration Verification Material  
  
Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3. Predicate device** The Boehringer Mannheim Elecsys CalCheck FSH is substantially equivalent to the Tosoh Medic AIA Pack for FSH. (K924863)
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- 4. Device Description** The Boehringer Mannheim Elecsys CalCheck FSH are manufactured using human serum albumin, follicle stimulating hormone, and stabilizers. The analyte is appropriately spiked into the calcheck matrix to the correct calcheck concentration levels. The calcheck are in process checked and quality controlled against the Enzymun<sup>®</sup> FSH assay kit calibrators (prepared using a similar procedure).
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## 510(k) Summary, Continued

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**5.  
Intended use**

The Boehringer Mannheim Elecsys CalCheck FSH is used to verify the calibration assignment for the Boehringer Mannheim Elecsys FSH assay.

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**6.  
Comparison  
to predicate  
device.**

**Performance Characteristics:**

- The Elecsys® CalCheck™ FSH were evaluated for value assignment and stability.
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