

K962573

JUL 22 1996



Diagnostics

## 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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Date Prepared: June 26, 1996

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**2. Device name** Proprietary name: Elecsys® PreciControl TSH Assay  
Common name: Control material  
Classification name: Enzyme controls (Assayed and Unassayed)

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**3. Predicate device** The Boehringer Mannheim Elecsys® PreciControl TSH is substantially equivalent to the Elecsys® TSH CalSet (K961491). The intended use has been changed to a quality control material.

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### 510(k) Summary, Continued

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**4. Device Description** Horse serum albumin control with recombinant Thyroid Stimulating Hormone for use in TSH assays.

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**5. Intended use** Control for Thyroid Stimulating Hormone assays.

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**6. Comparison to predicate device** The Boehringer Mannheim Elecsys® PreciControl TSH is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Elecsys® TSH CalSet (K961491).

The following table compares the Elecsys® PreciControl TSH with the predicate device, Elecsys® TSH CalSet.

**Similarities:**

- Same formulation.
- Same matrix: Horse serum matrix
- Same analyte: recombinant Thyroid Stimulating Hormone
- Standardization: World Health Organization (WHO-reference material # 80/558)
- Storage conditions: 2 - 8°C
- Application test system: Elecsys® 2010
- Reconstitution: none required, liquid
- Open vial stability: 4 weeks at 2 - 8°C
- Manufacturer: Boehringer Mannheim Germany

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### 510(k) Summary, Continued

6. Comparison to predicate device cont.

**Differences:**

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Feature	Elecsys® TSH CalSet	Elecsys ® PreciControl TSH
Target concentration	0 and 1.4µU/mL	0.18 µU/mL
Intended Use	Calibration of the Elecsys TSH Assay	Monitoring assays for TSH

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**Performance Characteristics:**

Feature	Elecsys® TSH CalSet	Elecsys ® PreciControl TSH
Open Vial Stability	4 weeks at 2 - 8°C	4 weeks at 2 - 8°C
Value Assignment	standardized against WHO-reference material (#80/558)	standardized against WHO-reference material (#80/558)

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