

JAN 30 1997

K970146

510(k) Summary
BOEHRINGER
MANNHEIM
CORPORATION



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
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Date Prepared: January 13, 1997

2. Device Name Proprietary name: Elecsys CalCheck Testosterone

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device The Boehringer Mannheim Elecsys CalCheck Testosterone is substantially equivalent to the currently marketed Tosoh Medics AIA-Pack FSH Calibration Verification Test. (K924863)

4. Device Description The Boehringer Mannheim Elecsys CalCheck Testosterone is manufactured using human serum albumin, testosterone, stabilizers, and preservatives. The analyte is appropriately spiked into the calcheck matrix to the correct calcheck concentration levels. The calchecks are in process checked and quality controlled against ID-GC/MS.

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5. Intended use The Boehringer Mannheim Elecsys CalCheck Testosterone is used to verify the calibration assignment for the Boehringer Mannheim Elecsys Testosterone assay.

6. Comparison to predicate device The Boehringer Mannheim Elecsys® CalCheck™ Testosterone 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 FSH Calibration Verification Test. (K924863)

Both products are intended to be used for the verification of calibration for analytes on automated immunoassay analyzers.

7. Performance Characteristics The Elecsys® CalCheck™ Testosterone was evaluated for value assignment and stability.
