APR -2 1997 K970984

BOEHRINGER MANNHEIM CORPORATION

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.

1. Submitter name, address, contact

Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, CA 94524-4117
(510) 674-0690 extension 8413
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Contact Person: Yvette Lloyd

Date Prepared: March 13, 1997

2. Device Name

Proprietary name: Elecsys CalCheck Progesterone

Common name: Calibration Verification Material

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

3. Predicate device

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

4. Device Description

The Boehringer Mannheim Elecsys CalCheck Progesterone is manufactured using human serum albumin, progesterone, stabilizers, and preservatives. The analyte is appropriately spiked into the calibrator matrix to the correct calibrator concentration levels. The calibrators are in process checked and quality controlled against the Enzymun® Progesterone assay kit calibrators (prepared using a similar procedure) which have been value assigned by comparison to ID-GC/MS.

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5. Intended use	The Boehringer Mannheim Elecsys CalCheck Progesterone is used to verify the calibration assignment for the Boehringer Mannheim Elecsys Progesterone assay.
6. Comparison to predicate device	The Boehringer Mannheim Elecsys® CalCheck™ Progesterone is substantially euivalent 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™ Progesterone was evaluated for value assignment and stability.