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510(k) Summary

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
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers

Date Prepared: November 15, 1996

2) Device name

Proprietary name: Enzymun-Test® PSA

Common name: tumor associated antigen immunological test system

Classification name: Prostate-specific antigen (PSA), immunological test system for the management of prostate cancer

3) Predicate device

We claim substantial equivalence to the Hybritech Tandem®-R PSA (P850048).

4) Device Description

The Enzymun-Test PSA test principle is an ELISA/1-step sandwich assay using streptavidin technology. The assay procedure is designed to run on the Boehringer Mannheim Automated Immunoassay Systems.

In the first incubation step (immunological reaction) the PSA in the sample reacts with the biotinylated anti-PSA antibodies, which are in turn bound to the streptavidin-coated tube wall. The PSA is also bound to the peroxidase (POD)-labeled monoclonal antibody (anti-PSA POD-conjugate) to form a sandwich complex. The quantity of antibody-PSA POD complex formed is a measure of the PSA content of the sample. The unbound POD-conjugate is removed along with serum constituents in the separation step.

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4) Device Description, (cont.)

The activity of the POD bound to the tube wall is determined photometrically after the addition of the chromogen and the substrate H_2O_2 (from sodium perborate). In the indicator reaction, the chromophore formed is a dark green cation whose concentration is directly proportional to the PSA concentration in the sample. The color intensity that develops within a fixed period of time is measured against the substrate/chromogen blank.

The test results are determined from a calibration curve derived using the standards provided in the kit.

5) Intended use

Enzyme-linked immunosorbent assay for the quantitative determination of Prostate-Specific Antigen (PSA) in serum and plasma.

6) Comparison to predicate device

The Boehringer Mannheim Enzymun-Test PSA is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Hybritech Tandem-R PSA.

The following table compares the Enzymun-Test PSA with the predicate device Hybritech Tandem-R PSA.

Similarities:

- Intended use: for the quantitative measurement of prostate-specific antigen (PSA) to aid in the prognosis and management of patients with prostate cancer.
- Both assays use mouse monoclonal antibodies to bind and detect PSA
- Both assays use 50 µl sample volume.

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6) Comparison to predicate device, (cont.)

Differences:

Feature	Enzymun-Test PSA	Hybritech Tandem-R PSA
Sample type	Human serum and plasma	Human serum
Detection method	Enzyme linked immunosorbent assay	Radioimmunoassay
Instrument required	ES 300 or other ES system	γ-PHOTON System or gamma counter
Calibration	Full calibration curve every 2 weeks with a 1 point recalibration with every run	Full calibration curve with every run

Performance Characteristics:

Feature	Enzymun-Test PSA	Hybritech Tandem-R PSA
Precision	NCCLS EP5-T2 protocol within run: Pool 1 Pool 2 Pool 3 TMI TMII N 63 63 63 63 63 $\bar{x}$ 0.28 3.07 39.64 1.19 6.43 CV 6.0 3.0 2.6 3.4 3.0 Total: Pool 1 Pool 2 Pool 3 TMI TMII N 63 63 63 63 63 $\bar{x}$ 0.28 3.07 39.64 1.19 6.43 CV 15.2 4.3 4.4 5.0 4.0	within run: (20 replicates from 3 runs) 1 2 3 N 60 60 60 $\bar{x}$ 2.98 6.99 36.34 CV 2.7 1.6 1.1 between run: 1 2 3 N 201 201 201 $\bar{x}$ 3.05 7.14 35.71 CV 5.6 3.2 3.7 inter-laboratory: 1 2 3 4 N 8 8 8 8 $\bar{x}$ 3.06 13.27 31.48 83.59 CV 5.56 5.12 4.42 2.64
Sensitivity	Lower detection limit: 0.05 ng/ml	Minimum detectable conc.: 0.15 ng/ml
Assay range (LDL to highest standard)	0.05 ng/ml - 50 ng/ml	0.15 ng/ml - 100 ng/ml
Interfering Substances hemoglobin bilirubin lipemia	No interference up to: 700 mg/dl 64.5 mg/dl 1250 mg/dl (Intralipid)	No interference up to: 200 mg/dl 25 mg/dl 2320 mg/dl