K982949

OCT 27 1998

# 510(k) Summary

# Elecsys® PSA on Elecsys 2010

**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 Road
Indianapolis, In 46250
(317) 845-3723

Contact Person: Priscilla A. Hamill

Date Prepared: August 14, 1998

**2. Device name**

Proprietary name: Elecsys® PSA Assay

Common name: Electrochemiluminescence assay for the determination of Prostate-Specific Antigen (PSA).

Classification name: System, Test , Prostate-Specific antigen

**3. Predicate device**

We claim substantial equivalence to the Elecsys® PSA 1st Gen. (K964351/S1).

**4. Device Description**

The Elecsys® test principle is based on sandwich principle. Total duration of assay: 18 minutes (37° C).

- 1st incubation (9 minutes): Sample (20 µL), a biotinylated monoclonal PSA-specific antibody (70 µL), and a monoclonal PSA-specific antibody labeled with a ruthenium complex (70 µL) react to form a sandwich complex.
- 2nd incubation (9 minutes): After addition of streptavidin-coated microparticles (40 µL), the entire complex is bound to the solid phase via interaction of biotin and streptavidin.

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## 510(k) Summary, continued

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|---|---|
| **4. Device Description (con't)** | •The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier (0.4 second read frame).<br>•Results are determined via a calibration curve which is instrument-generated by 2-point calibration and a master curve provided via the reagent bar code. |
| **5. Intended use** | Immunoassay for the in vitro quantitative determination of Prostate-Specific Antigen in human serum and plasma. The Elecsys PSA assay is further indicated for serial measurement of PSA to aid in the management of cancer patients.<br>The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 2010 immunoassay analyzer |
| **6. Comparison to predicate device** | The Boehringer Mannheim, a Roche Diagnostics Company Elecsys® PSA, 1st Gen. is cleared for use on the Elecsys 2010 immunoassay analyzer (K964351/S1). The application of the Elecsys® PSA, 2nd Gen. Assay on the Elecsys 2010 immunoassay analyzer is substantially equivalent to the Elecsys PSA, 1st Gen. assay. |

The following table compares the Elecsys® PSA, 2nd Gen. with the predicate device, Elecsys® PSA, 1st Gen.. Specific data on the performance of this test for Elecsys 2010 and Elecsys 1010, 2nd Gen. (separate premarket notification) have been incorporated into the draft labeling in attachment 5.

**Similarities**:

- Intended Use: Immunoassay for the in vitro quantitative determination of prostate-specific antigen. The assay is further indicated for serial measurement of PSA to aid in the management of cancer patients.
- Assay range: 0-100 ng/ml
- Assay methodology: Sandwich immunoassay
- Cross-Reactivity: None to PAP and ACT
- Specificity: Equimolar recognition of PSA-ACT and free PSA
- Application to Elecsys 1010 and 2010 immunoassay analyzers
- Reaction temperature and incubation times
- Performance specifications

**Differences**:

- Capture antibody
- Sample and reagent volumes

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**Performance Characteristics:**

| Feature | Elecsys PSA, 2nd Gen. | | | Elecsys PSA, 1st Gen. | | |
|---|---|---|---|---|---|---|
| Precision | Modified NCCLS (ng/mL): | | | Modified NCCLS (ng/mL): | | |
| Level | HS1 | HS2 | HS3 | HS1 | HS2 | HS3 |
| N | 60 | 60 | 60 | 60 | 60 | 60 |
| Mean | 0.30 | 4.76 | 51.1 | 0.29 | 13.9 | 48.5 |
| Within-Run %CV | 1.8 | 2.5 | 2.2 | 1.5 | 1.8 | 1.6 |
| Total %CV | 2.4 | 2.9 | 3.8 | 2.9 | 2.3 | 2.3 |
| | Modified NCCLS (ng/mL): | | | Modified NCCLS (ng/mL): | | |
| | PC-TM1 | PC-TM2 | | PC-TM1 | PC-TM2 | |
| N | 60 | 60 | | 60 | 60 | |
| Mean | 2.33 | 17.2 | | 1.88 | 14.0 | |
| Within-Run %CV | 2.5 | 2.3 | | 1.1 | 1.2 | |
| Total %CV | 2.7 | 2.9 | | 2.1 | 2.2 | |

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**F. Substantial equivalence, cont.**

**Performance Characteristics:**

| Feature | Elecsys PSA, 2nd Gen. | Elecsys PSA, 1st Gen. |
|---|---|---|
| Sensitivity<br>Analytical<br>Functional | <br>0.002 ng/mL<br>0.03 ng/mL | <br>0.002 ng/mL<br>0.03 ng/mL |
| Linearity | 0.002 - 100 ng/mL (with a deviation from a linear line of ±10%) | 0.002 - 100 ng/mL (with a deviation from a linear line of ±10%) |
| Method Comparison | Vs Elecsys PSA, 1st Gen. (on 2010)<br><br><u>Least Squares</u><br>y=1.0098x + 0.734<br>r=0.998<br>N=108<br><br><u>Passing Bablok</u><br>y=1.0335x + 0.219<br>r=0.998<br>N=108 | |
| Hook Effect | No Hook Effect up to 17,000 ng/ml PSA | No Hook Effect up to 15,000 ng/ml PSA |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 27 1998

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Roche Diagnostics,
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Tennessee 46250

Re: K982949
Trade Name: Elecsys® PSA Assay
Regulatory Class: II
Product Code: LTJ
Dated: August 14, 1998
Received: August 21, 1998

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): N/A K982949

Device Name: Elecsys® PSA Assay

Indications For Use:

Immunoassay for the in vitro quantitative determination of prostate-specific antigen (PSA) in human serum and plasma. The Elecsys PSA assay is further indicated for serial measurement of PSA to aid in the management of cancer patients.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 2010 immunoassay analyzer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982949