JUN 14 1996 K961481

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.

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1) Submitter name, address, contact

Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2327

Contact Person: John D. Stevens

Date Prepared: April 17, 1996

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2) Device name

Proprietary name: Elecsys 2010® analyzer

Common name: immunoassay analyzer

Classification name: Discrete photometric analyzer for clinical use

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3) Predicate device

We claim substantial equivalence to the Boehringer Mannheim ES300 Immunoassay system.

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4) Device Description

The Elecsys 2010 analyzer is a fully automated, random access, computer controlled analytical system for quantitative and qualitative determinations of analytes in body fluids

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5) Intended use

The Elecsys 2010 analyzer is intended to be used for the in vitro quantitative and qualitative analysis of analytes in body fluids.

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510(k) Summary Elecsys® 2010 Analyzer, Continued

6) Comparison to predicate device

The Boehringer Mannheim Elecsys 2010 analyzer is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ES300 Immunoassay analyzer.

The following table compares the Elecsys 2010 with the predicate device. Specific data on the performance of the system have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in provided in attachment 6.

Similarities:

Feature	Elecsys 2010 Analyzer	ES300 Analyzer
Intended use	Intended for the in vitro quantitative/qualitative determination of analytes in body fluids	Same
Number of reagents	Up to 2	Same
Sample detection	Liquid level detection and clot detection	Same
Sample type	Serum and plasma	Same
Host interface	RS232C bidirectional	Same

Differences:

Feature	Elecsys 2010 analyzer	ES300 analyzer
Operating principle	Electrochemiluminescence immunoassay method type	Enzyme-linked immunosorbent assay method type
Detection system	Flow through electrochemiluminescence detection cell	Flow through cuvette with halogen lamp light source
Sample positions	30 positions for samples, controls and calibrators	150 positions for samples, controls and calibrators
Sample volume / test	10 to 50µL	5 to 200 µL
Reagent positions	15 reagent positions 2 diluent/reagent positions 1 BlankCell position	12 reagent positions 1 cleaning solution 2 universal substrate

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510(k) Summary, Elecsys 2010® Analyzer Continued

6) Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys 2010 vs. ES300 Least Squares Regression
Method Comparison T4	Y = 1.02x +0.85 SEE = 5.39 r = 0.947
Method Comparison FT4	Y = 0.954X + 0.18 SEE + 1.11 r + 0.981
Method Comparison TSH	Y = 1.09X + 0.14 SEE = 0.798 r = 0.991; n = 132
Method Comparison T-Uptake	Y = 0.99X - 0.03 SEE = 0.04 r = 0.908; n = 319
Method Comparison hCG	Y = 1.35X - 9.21 SEE = 17.50 r = 0.989; n = 64
Method Comparison Troponin-T	Y = - 0.033 + 0.996 SEE = 0.547 r = 0.969; n = 54

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 7 2000

Ms. Kay Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K961481
Trade Name: Elecsys 2010 Analyzer
Regulatory Class: II
Product Code: CDX, CEC, DHA, JJE, JLW, KHQ, MMI
Dated: May 29, 1996
Received: May 30, 1996

Dear Ms. Taylor:

This letter corrects our substantially equivalent letter of June 14, 1996, regarding the Elecsys 2010 Analyzer. The Elecsys 2010, associated reagents, and subsequent models within the Elecsys Family of analyzers referenced in K961481 were only classified as a class I device. Elecsys analyzers with their associated reagents are considered combination devices and carry the highest classification as stated in Blue Book memo #K86-3 "When such a device is found to be SE, it combines devices from different classes and is classified in the highest of the predicate device classifications."

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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): K961481

Device Name: Elecsys® 2010 Analyzer

Indications for Use:

The Elecsys 2010 analyzer is an immunoassay analyzer intended for the in vitro quantitative and qualitative determination of analytes in human serum and plasma

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K961481

(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)

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