FEB 8 1999

K984326

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.

Submitter name, address, contact

Roche Diagnostics, doing business in the US as Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
(317) 576-3723

Contact person: Priscilla A. Hamill

Date prepared: December 2, 1998

Device name

Proprietary name: Elecsys® IgE Test

Common name: IgE

Classification name: Immunoglobulins A, G, M, D, and E immunological test system

Predicate device

We claim substantial equivalence to the Boehringer Mannheim Enzymun-Test® IgE.

Device description

The Elecsys® IgE test is based on the sandwich principle of heterogeneous immunological complex formation.

First Step: Biotinylated monoclonal antibodies (R1) and ruthenium labeled antibodies (R2), both specific for IgE, bind IgE present in the sample forming a sandwich complex
Second Step: Microparticles coated with streptavidin (M) bind the biotin portion of the complex and are captured magnetically onto the surface of the electrode. Application of a voltage to the electrode induces chemiluminescent emission, which is measured by a photomultiplier.

510(k) Summary, Continued

Intended use

For in vitro quantitative determination of immunoglobulin E in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.

Comparison to the predicate device

Similarities: The following table compares Boehringer Mannheim ® IgE Test with the predicate device. Specific data on the performance of the test have been incorporated into the draft labeling in Attachment 5. Labeling for the predicate device is provided in Attachment 6.

Feature	Elecsys® IgE Test	Enzymun-Test® IgE.
Intended use	For the quantitative determination of IgE in human serum and plasma on the Elecsys 1010 and 2010 immunoassay analyzers.	For the quantitative determination of IgE in human serum and plasma on automated immunoassay analyzers
Indications for use	An aid in the diagnosis of allergic diseases	An aid in the diagnosis of allergic diseases
Sample type	Human serum, plasma	Human serum, plasma
Assay reaction principle	Sandwich principle, Heterogeneous immunological complex formation	Sandwich principle, Heterogeneous immunological complex formation, ELISA
Standard-ized against	WHO Standard	WHO Standard

Continued on next page

Comparison to the predicate device (cont.)

Differences: The following differences between Elecsys® IgE Test and the predicate device are not significant for purposes of determining substantial equivalence.

Feature	Elecsys® IgE Test	Enzymun-Test® IgE.
Measure-ment approach	Electrochemiluminescence	Photometric
Instrument required	Boehringer Mannheim Elecsys automated immunoassay analyzer	Boehringer Mannheim ES 300/300 AL automated immunoassay analyzers
Reagent Formula-tion	Liquid; ready to use	Lyophilized; reconstitution required

Performance characteristics: The performance of the Elecsys® IgE Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® IgE.

Feature	Elecsys® IgE Test	Enzymun-Test® IgE.
Precision	Within-Run %CV 3.6% at 5.18 IU/mL 2.1% at 105 IU/mL 2.8% at 197 IU/mL 3.2% at 398 IU/mL 2.4% at 1010 IU/mL Total %CV 4.2% at 5.18 IU/mL 1.9% at 105 IU/mL 3.9% at 197 IU/mL 3.9% at 398 IU/mL 3.1% at 1010 IU/mL	Within-Run %CV 2.1% at 102.7 IU/mL 2.1% at 244.1 IU/mL 2.8% at 375.4 IU/mL Total %CV 3.4% at 102.7 IU/mL 3.4% at 244.1 IU/mL 3.6% at 375.4 IU/mL
Lower Detection Limit	0.10 IU/mL	1.44 IU/mL
Measuring Range	0.10-4000 IU/ml	1.44-500 IU/ml

Comparison to the predicate device (cont.)

Performance characteristics: continued

Feature	Elecsys® IgE Test	Enzymun-Test® IgE.
Specificity	No cross-reactivity with the immunoglobulins G, A and M was detected.	No cross-reactions with IgG, IgA and IgM was detected.
Method comparison	Elecsys IgE vs Enzymun-Test IgE **Passing/Bablok** y = -0.53 + 0.97x r = 1.0 SD (md68) = 2.42 N = 188 **Linear regression** y = -1.85 + 1.01x r = 1.0 Sy.x = 5.86 N = 188	
Interfering substances: Bilirubin Hemoglobin Lipemia Biotin	No interference at: <37 mg/dL <1.1 g/dL <2200 mg/dL <100 ng/mL	No interference at: <64.5 mg/dL <1 g/dL <1250 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 8 1999

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K984326
Trade Name: Elecsys IgE Test
Regulatory Class: II
Product Code: JHR
Dated: December 2, 1998
Received: December 3, 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.

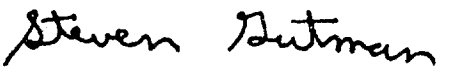
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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): _____

Device Name: Elecsys® IgE Test

Indications for Use: For in vitro quantitative determination of immunoglobulin E in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.

Determination of total serum IgE is useful as an aid in the diagnosis of allergic disease.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984326

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