510(k) Summary

NOV 1 9 2002

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 Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3544

Contact Person: Kay A. Taylor

Date Prepared: September 12, 2002

Device Name

Proprietary name: Elecsys® proBNP Immunoassay

Common name: proBNP test

Classification name: Test, Natriuretic Peptide

Device Description

A device for the measurement of human proBNP in serum or plasma.

Intended use

For the quantitative determination of N-terminal pro-Brain natriuretic peptide.

Indications for Use

An aid in the diagnosis of individuals suspected of having congestive heart failure.

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Substantial equivalence

The Elecsys proBNP Immunoassay is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Biosite Triage BNP Test cleared under K003475. Both products are intended for use in the quantitative determination of brain natriuretic peptides.

Substantial equivalence - comparison

The following table compares the Roche Elecsys proBNP Immunoassay with the predicate device.

Feature	Elecsys proBNP Immunoassay	Biosite Triage BNP Test (predicate)
Intended Use	For the quantitative determination of N-terminal pro-Brain natriuretic peptide.	Measurement of B-Type Natriuretic Peptide (BNP).
Indication for Use	An aid in the diagnosis of individuals suspected of having congestive heart failure.	An aid in the diagnosis of congestive heart failure in patients age 55 and older
Assay Protocol	Electrochemiluminescent immunoassay	Fluorescence Immunoassay
Traceability / Standardization	Reference standard - purified synthetic NTG-proBNP (1-76) in human serum matrix	Purified BNP preparation based on mass of analyte present in EDTA plasma
Calibration Interval	E170/E2010 • After 1 month when using the same reagent lot • After 7 days when using the same reagent kit E1010 • With every reagent kit • After 7 days (20-25°C) • After 3 days (25-32°C)	Each kit
Sample Type	Human serum and plasma	Human whole blood and EDTA plasma
Calibrator	Elecsys proBNP CalSet	Electronic code chip
Controls	Elecsys PreciControl proBNP	Triage® BNP Controls

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Feature	Elecsys proBNP Immunoassay	Biosite Triage BNP Test (predicate)
Reagent Stability	Unopened • Up to stated expiration date stored at 2-8°C Opened • 12 weeks at 2-8° • 8 weeks on E170 • 8 weeks on E2010 • 4 weeks on E1010 (20-25° ambient temp - up to 20 hours opened in total)	• Up to stated expiration date when stored at 2-8°C. • 14 days at ambient temperature
Expected Values	• Age and sex-related descriptive statistics provided • Cut-offs of 125 pg/ml for patients younger than 75 years and 450 pg/ml for patients 75 years and older are recommended.	• Age and sex-related descriptive statistics provided • Cut-off 100 pg/mL recommended
Instrument	Elecsys family of analyzers (Elecsys 1010, Elecsys 2010 and Elecsys E170 MODULAR Analytics Immunoassay Analyzers)	Triage® Meter
Measuring Range	5-35,000 pg/mL	5-1300 pg/mL

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Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys proBNP Immunoassay and the predicate device are compared in the table below.

Feature	Elecsys proBNP Immunoassay	Biosite Triage BNP Test (predicate)
Precision	E170 • Within-run 0.8-1.1 %CV from 208-13,682 pg/mL • Total 3.6-5.8% CV from 200-13143 pg/mL E101/2010 • Within-run 1.8-2.7 %CV from 175-4962 pg/mL • Total 2.2-3.2 %CV from 175-4962 pg/mL	• Average within-run 9.4-15.2 %CV from 28.8-1080.4 pg/mL • Average total 10.1-16.2 %CV
Hook Effect	No high dose hook effect up to 300,000 pg/mL	NA
Analytical sensitivity (LDL)	5 pg/mL	5 pg/mL
Limitations/Warnings/Precautions	• No interference from bilirubin up to 35 mg/dL • No interference from hemoglobin up to 1.4 g/dL • No interference from triglycerides up to 4000 mg/dL • No interference with biotin up to 30 ng/mL • No interference from rheumatoid factor up to 1500 IU/mL • In patients receiving high biotin doses > 5 mg/dL, sample should not be taken until 8 hours after administration • Rare occurrence of interference from high titers of anti-streptavidin and ruthenium • Use in conjunction with patient medical history, clinical exam and other findings	• No interference from bilirubin up to 20 mg/dL. • No interference from hemoglobin up to 10000 mg/dL • Severely hemolyzed specimens should be avoided. • No interference from triglycerides up to 1000 mg/dL • No interference from cholesterol up to 1000 mg/dL • Blood concentrations of natriuretic peptides may be elevated in patients with acute myocardial infarction, patients that are candidates for renal dialysis, and patients that have undergone renal dialysis • Results should be evaluated in the context of all the clinical and laboratory data available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor
Regulatory Program Principal
Centralized Diagnostic Submissions
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

NOV 1 9 2002

Re: k022516
Trade/Device Name: Elecsys® proBNP Immunoassay
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC; JIT; JJX
Dated: October 23, 2002
Received: October 24, 2002

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K022516

Device Name:

Elecsys® proBNP Immunoassay

Indications For Use:

Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. The Elecsys proBNP Immunoassay is intended for use as an aid in the diagnosis of individuals suspected of having congestive heart failure.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys family of analyzers.

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

(Optional Format 1-2-96)

Ian Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022516