DEC 5 2005

K051382

Elecsys® proBNP Immunoassay
Expanded Intended Use Submission

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

Contact Person: Theresa M. Ambrose

Date Prepared: Nov 28, 2005

Device Name

Proprietary name: Elecsys® proBNP Immunoassay

Common name: proBNP test

Classification name: Test, Natriuretic Peptide

Description

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

Intended use

Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain Natriuretic Peptide in human serum and plasma.

Indications for Use

Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome or congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.

Substantial equivalence

The device and test method contained within this premarket notification and described in the labeling is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Elecsys proBNP (K032646).

Substantial equivalence – comparison

The following table compares the Elecsys proBNP Test System with the predicate device.

Table 3 - Comparison to Predicate Device

Feature	Elecsys proBNP Expanded Intended Use	Elecsys proBNP (K032646) Predicate
Intended Use	Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic Peptide in human serum and plasma.	same
Indication for Use	Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome or congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.	Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure.
Assay Protocol	Electrochemiluminescent Immunoassay	Same
Traceability / Standardization	Reference standard - purified synthetic NTG-proBNP (1-76) in human serum matrix	Same
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)	Same
Sample Type	Human serum and plasma	Same

Feature	Elecsys proBNP Expanded Intended Use	Elecsys proBNP (K032646) 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)	Same
Calibrator	Elecsys proBNP CalSet	Same
Controls	Elecsys PreciControl Cardiac	Elecsys PreciControl proBNP Elecsys PreciControl Cardiac
Result Interpretation	125 pg/ml for patients younger than 75 years and 450 pg/ml for patients 75 years and older.	Same
Instrument	Elecsys 1010, Elecsys 2010 and MODULAR analytics E170 family of analyzers	Same
Measuring Range	5-35,000 pg/mL	Same

Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys proBNP Immunoassay and the predicate table below.

Table 4 - Comparison to Predicate Device - Performance Characteristics

Feature	Elecsys proBNP (add'l indication)	Elecsys proBNP (K022516)
Precision	E170 - Within run 0.9%CV @ 474 pg/mL 1.1%CV @ 8005 pg/mL 0.9%CV @ 13682 pg/mL E170 - Total 5.8%CV @ 494 pg/mL 4.1%CV @ 7827 pg/mL 3.7%CV @ 13143 pg/mL E1010/2010 – Within run 2.7%CV @ 175 pg/mL 2.4%CV @ 355 pg/mL 1.9%CV @ 1068 pg/mL 1.8%CV @ 4962 pg/mL E1010/2010 – Total 3.2%CV @ 175 pg/mL 2.9%CV @ 355 pg/mL 2.6%CV @ 1068 pg/mL 2.3%CV @ 4962 pg/mL	Same

Feature	Elecsys proBNP (add'l indication)	Elecsys proBNP (K022516)
Hook Effect	No effect up to 300,000 pg/ml	Same
Analytical Sensitvity	5 pg/mL	Same
Limitations	• 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	Same

Support for claim

Three literature articles were provided in support of the expanded intended use:

1. Schnabel R, Rupprecht HJ, Lackner KJ, Lubos E, Bickel C, et al. Analysis of N-Terminal-pro-Brain Natriuretic Peptide and C-Reactive Protein for Risk Stratification in Stable and Unstable Coronary Artery Disease: Results from the Athero*Gene* Study. *European Heart Journal*, 2005. 26(3):241-249.
2. Kragelund C, Groenning B, Kober L, Hildebrandt P and Steffensen R. N-Terminal Pro-B-Type Natriuretic Peptide and Long-Term Mortality in Stable Coronary Heart Disease. *The New England Journal of Medicine*, 2005. 352(7):666-675.
3. Ndrepepa G, Braun S, Niemoller K, Mehilli J, von Beckerath N, et al. Prognostic Value of N-Terminal Pro-Brain Natriuretic Peptide in Patients with Chronic Stable Angina. *Circulation*, 2005. 112:2102-2107.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 5 2005

Theresa M. Ambrose, PhD, RAC
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: k051382
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
Dated: October 14, 2005
Received: October 17, 2005

Dear Dr. Ambrose:

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 (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k051382**

Device Name: Elecsys proBNP Immunoassay

Indications For Use:

For the in vitro quantitative determination of N-terminal proBrain natriuretic peptide in human serum and plasma.
Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome or congestive heart failure . The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010, Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers

Prescription Use ___XXX___ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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