K083260

OCT 16 2009

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
9115 Hague Rd
Indianapolis IN 46250
(317) 521 - 3225

Contact person: Jack Rogers, Regulatory Affairs Principal

Date prepared: September 30, 2009

Device Name

Proprietary name: 1) Elecsys Myoglobin Immunoassay
2) Elecsys Myoglobin STAT Immunoassay

Common name: 1) Myoglobin Immunoassay
2) Myoglobin STAT Immunoassay

Classification name: Myoglobin immunological test system

Classification

21 CFR 866.5680; Class 2

Device Description

The Elecsys Myoglobin Immunoassay includes two applications of the same reagents with different incubation times of 18 minutes (Myoglobin assay) and 9 minutes (Myoglobin STAT assay). The assay is a two-step sandwich immunoassay, using two different monoclonal antibodies directed against human Myoglobin, with streptavidin microparticles, and electrochemiluminescence detection. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

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Intended Use / Indications for Use

Elecsys Myoglobin Immunoassay

Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma. The Elecsys Myoglobin assay is intended to aid in the rapid diagnosis of heart and renal disease.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and cobas e immunoassay analyzers.

Elecsys Myoglobin STAT Immunoassay

Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma. The Elecsys Myoglobin STAT assay is intended to aid in the rapid diagnosis of heart and renal disease.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and cobas e immunoassay analyzers.

Predicate Device

The Elecsys Myoglobin and Elecsys Myoglobin STAT assays are substantially equivalent to the Elecsys Myoglobin STAT assay (K983176).

Substantial Equivalence – Device Comparison

The following table compares the new Elecsys Myoglobin and Elecsys Myoglobin STAT assays with the predicate device Elecsys Myoglobin STAT Assay (K983176).

Feature	Elecsys Myoglobin and Myoglobin STAT	Elecsys Myoglobin STAT (K983176) Predicate
Intended Use / Indications for Use	Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma. The assay is intended to aid in the rapid diagnosis of heart and renal disease. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and cobas e immunoassay analyzers.	Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.
Assay Protocol	Electrochemiluminescence immunoassay	Electrochemiluminescence immunoassay
Specimen Type	Human serum and plasma	Human serum and plasma

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Substantial Equivalence – Device Comparison (continued)

Feature	Elecsys Myoglobin and Myoglobin STAT	Elecsys Myoglobin STAT (K983176) Predicate
Measuring Range	21-3000 ng/mL defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as <21 ng/ml. Values above the measuring range are reported as >3000 ng/mL (or up to 3000 ng/mL for 10-fold diluted samples)	15-3000 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as <15 ng/ml. Values above the measuring range are reported as ≥ 3000 ng/mL (or up to 3000 ng/mL for 10-fold diluted samples)
Expected values	Men 28-72 ng/ml Women 25-58 ng/ml Based on a study with Elecsys Myoglobin STAT assay	Men < 72 ng/ml Women < 51 ng/ml Based on a study with Tina-quant Myoglobin.
Traceability / Standardization	**Myoglobin assay** The Elecsys Myoglobin assay has been standardized against the Elecsys Myoglobin STAT assay. **Myoglobin STAT assay** This method has been standardized against an in-house reference preparation.	Calibrated against Tina-quant Myoglobin which was calibrated against a nephelometric method.
Dilution	Recommended dilution factor is 1:10. The concentration of the diluted sample must be >50 ng/mL.	Recommended dilution factor is 1:10. The concentration of the diluted sample must be >200 ng/mL.

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Substantial Equivalence – Device Comparison (continued)

Feature	Elecsys Myoglobin and Myoglobin STAT	Elecsys Myoglobin STAT (K983176) Predicate
Performance Characteristics		
Precision	**Myoglobin assay** Repeatability (within run) 2.0% CV @ 32.0 ng/mL 1.0% CV @ 87.0 ng/mL 1.8% CV @ 1020 ng/mL 1.1% CV @ 1194 ng/mL 1.8% CV @ 2474 ng/mL Intermediate Precision (Total) 2.3% CV @ 32.0 ng/mL 1.5% CV @ 87.0 ng/mL 2.5% CV @ 1020 ng/mL 1.8% CV @ 1194 ng/mL 2.2% CV @ 2474 ng/mL **Myoglobin STAT assay** Repeatability (within run) 1.7% CV @ 33.9 ng/mL 1.2% CV @ 90.1 ng/mL 1.8% CV @ 1016 ng/mL 1.1% CV @ 1171 ng/mL 2.2% CV @ 2468 ng/mL Intermediate Precision (Total) 2.1% CV @ 33.9 ng/mL 1.3% CV @ 90.1 ng/mL 2.2% CV @ 1016 ng/mL 1.3% CV @ 1171 ng/mL 2.6% CV @ 2468 ng/mL	Repeatability (within run) 2.1% CV @ 43.0 ng/mL 1.3% CV @ 82.5 ng/mL 2.9% CV @ 237 ng/mL 2.9% CV @ 523 ng/mL 1.9% CV @ 672 ng/mL 3.4% CV @ 1147 ng/mL 5.3% CV @ 3056 ng/mL Intermediate Precision (Total) 2.6% CV @ 43.0 ng/mL 1.6% CV @ 82.5 ng/mL 3.6% CV @ 237 ng/mL 3.8% CV @ 523 ng/mL 2.3% CV @ 672 ng/mL 4.0% CV @ 1147 ng/mL 6.7% CV @ 3056 ng/mL

Substantial Equivalence – Device Comparison (continued)

Feature	Elecsys Myoglobin and Myoglobin STAT	Elecsys Myoglobin STAT (K983176) Predicate
Performance Characteristics (continued)		
Method Comparison	**Myoglobin assay** N = 129 Range: 24 to 2945 Passing/Bablok Slope = 1.03 Intercept = 6.26 r = 0.987 Linear Regression Slope = 1.02 Intercept = 14.5 r = 0.999 Deming Regression Slope = 1.00 Intercept = 13.9 r = 0.999 **Myoglobin STAT assay** N = 139 Range: 23 to 2523 Passing/Bablok Slope = 1.04 Intercept = -2.08 r = 0.955 Linear Regression Slope = 1.08 Intercept = -9.60 r = 0.988 Deming Regression Slope = 1.09 Intercept = -14.6 r = 0.997	N = 398 Range: 26 to 595 Passing/Bablok Slope = 1.01 Intercept = -0.135 r = 0.996 Linear Regression Slope = 0.997 Intercept = 1.284 r = 0.996
Limit of Blank	18 ng/mL	Not Reported
Limit of Detection	21 ng/mL	21 ng/mL
Limit of Quantitation	25 ng/mL	Not Reported

Substantial Equivalence – Device Comparison (continued)

Feature	Elecsys Myoglobin and Myoglobin STAT	Elecsys Myoglobin STAT (K983176) Predicate
Performance Characteristics (continued)		
Interferences (limitations)	Hemolytic no effect up to 1.4 g/dL Biotin no effect up to 50 ng/mL Lipemia no effect up to 2200 mg/dL Bilirubin no effect up to 65 mg/dL Rheumatoid factor no effect up to 1500 IU/mL	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Roche Diagnostics
Centralized Diagnostics
c/o Mr. Jack Rogers
Regulatory Affairs Principal
RPD Regulatory Submissions
9115 Hague Road
Indianapolis, IN 46250

OCT 16 2009

Re: k083260
Trade Name: Elecsys® Myoglobin Immunoassay, Elecsys® Myoglobin STAT Immunoassay
Regulation Number: 21 CFR §866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Codes: DDR
Dated: September 30, 2009
Received: October 1, 2009

Dear Mr. Rogers:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, 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: K083260

Device Name: Elecsys Myoglobin Immunoassay

Indications For Use:

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Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 083260

Indications for Use

510(k) Number: K083260

Device Name: Elecsys Myoglobin STAT Immunoassay

Indications For Use:

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