K040733

MAY 17 2004

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 Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Theresa M. Ambrose

Date Prepared: May 11, 2004

Device Name

Proprietary name: Elecsys Troponin T ® STAT test

Common name: Troponin T test

Classification name: Immunoassay method, troponin subunit

Predicate device

The Elecsys Troponin T STAT is substantially equivalent to the currently marketed Elecsys ® Troponin T STAT (K984105).

Device Description

The Elecsys Troponin T STAT is a two step sandwich immunoassay with streptavidin micro particles and electrochemiluminescence detection, for the measurement of human TnT in serum or plasma.

Intended use

Immunoassay for the in vitro quantitative determination of troponin T in human serum and plasma. Elecsys Troponin T can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g., acute myocardial infarction. The test is further indicated for the risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. The test may also be useful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac Troponin T. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys family of immunoassay analyzers.

510(k) Summary, Continued

Comparison to predicate device

The Elecsys Troponin T STAT is substantially equivalent to the currently marketed currently marketed Elecsys ® Troponin T STAT (K984105). The below tables compare Elecsys® Troponin T STAT with the predicate device, Elecsys® Troponin T STAT (K984105)

Character-istic	Elecsys® Troponin T STAT (modified intended use)	Predicate device Elecsys® Troponin T STAT (K984105)
Intended Use	Immunoassay for the in vitro quantitative determination of troponin T in human serum and plasma. Elecsys Troponin T can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g., acute myocardial infarction. The test is further indicated for the risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. The test may also be useful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac Troponin T. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys family of immunoassay analyzers.	Immunoassay for the in vitro quantitative determination of troponin T in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys family of immunoassay analyzers.

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Predicate device (continued)

Character-istic	Elecsys® Troponin T STAT (modified intended use)	Predicate device Elecsys® Troponin T STAT (K984105)
Indications for Use	Troponin T (TnT) is a component of the contractile apparatus of the striated musculature. Although the function of TnT is the same as in all striated muscles, TnT originating exclusively from the myocardium (cardiac TnT, molecular weight 39.7 kD) clearly differs from skeletal muscle TnT. As a result of its high tissue sensitivity, cardiac troponin T (cTnT) is a cardiospecific, highly sensitive marker for myocardial damage. In cases of acute myocardial infarction, troponin T levels rise about 3-4 hours after the occurrence of cardiac symptoms and can remain elevated for up to 14 days. The determination of cTnT in serum is an important component in the diagnosis of myocardial ischemia, e.g. AMI and myocarditis, as well as in monitoring the course of unstable angina pectoris and assessing the associated risk. Comparative studies on 770 patients confirm the prognostic utility of cTnT. It has also been shown that cTnT-positive patients benefit particularly from antithrombotic therapy strategies (e.g. low molecular weight heparin, GPIIb/IIIa antagonists). Elevated serum cTnT values are detectable in about 30% of patients suffering from renal failure (e.g. chronic hemodialysis patients). The cTnT detected in these patients is of cardiac origin. It has been demonstrated e.g. with RT-PCR, that cTnT is not expressed in regenerated skeletal musculature of patients with renal failure. Clinical data increasingly demonstrate that such patients have a high risk of subsequently suffering cardiovascular complications.	Same

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Predicate device (continued)

Characteristic	Elecsys® Troponin T STAT (modified intended use)	Predicate device Elecsys® Troponin T STAT (K984105)
Assay principle	Electrochemiluminescent immunoassay	Same
Traceability/ standardization	Standardized against the 2nd generation Elecsys Troponin T test	Same
Calibration interval	Elecsys 2010 • After 1 month when using the same reagent lot • After 7 days when using the same reagent kit on the analyzer Elecsys 1010 • With every reagent kit • After 7 days (20-25 °C) • After 3 days (25-32 °C)	Same
Sample type	Human serum, EDTA and citrate plasma.	Same
Reagent stability	Unopened • Up to the stated expiration date at 2-8 °C After opening • 12 weeks at 2-8 °C • 8 weeks on Elecsys 2010 • 8 weeks on Elecsys 1010 (20-25 °C; up to 20 hours opened in total)	Same
Calibrator	Elecsys Troponin T STAT CalSet	Same
Controls	Elecsys PreciControl Troponin T or Elecsys PreciControl Cardiac.	Same
Duration of assay	9 minutes	same

Substantial equivalence: performance characteristics

The performance characteristics of the Elecsys® Troponin T STAT test and the predicate device are compared in the table below.

Characteristic	Elecsys® Troponin T STAT (modified intended use)	Predicate device Elecsys® Troponin T STAT (K984105)
Measuring range	0.010 – 25.00 ng/mL	Same
Precision	Within-run (human serum) • 1.1% CV at 0.47 ng/mL • 1.1% CV at 2.63 ng/mL • 1.4% CV at 11.5 ng/mL Within-run (PreciControl) • 4.2% CV at 0.10 ng/mL • 3.0% CV at 5.07 ng/mL Total (human serum) • 5.8% CV at 0.47 ng/mL • 5.4% CV at 2.63 ng/mL • 5.7% CV at 11.5 ng/mL Within-run (PreciControl) • 9.3% CV at 0.10 ng/mL • 6.0% CV at 5.07 ng/mL	Same
Hook effect	No hook effect up to 400 ng/mL	Same
Analytical sensitivity	Lower detection limit: 0.01 ng/mL Lowest concentration giving 10 % CV: 0.03 ng/mL	Same

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Substantial equivalence: performance characteristics (continued)

Characteristic	Elecsys® Troponin T STAT (modified intended use)	Predicate device Elecsys® Troponin T STAT (K984105)

Limitations – interference	No interference from • icterus up to 27 mg/dL bilirubin • hemolysis up to 0.1 g/dL, • Lipemia up to 1500 mg/dL Intralipid • Biotin up to 50 ng/mL • Rheumatoid factor up to 2000 U/mL Falsely depressed results are obtained when using samples with higher hemoglobin concentrations. Plasma samples collected with heparin or oxalate/fluoride revealed sample-dependent low TnT values compared to results obtained on serum samples. Contains additives to minimize the effects of interference due to • Monoclonal mouse antibodies • Antibodies to streptavidin Extremely high titers of antibodies to ruthenium can cause interference. Results should be assessed in conjunction with the patient's medical history, clinical examination, and other findings	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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MAY 17 2004

Theresa M. Ambrose, PhD, DABCC, FACB, RAC
Regulatory Principial
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250

Re: k040733
Trade/Device Name: Elecsys Troponin T STAT
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: March 19, 2004
Received: March 22, 2004

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, D.V.M.

Jean M. Cooper, MS, D.V.M.
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): K040733

Device Name: Elecsys Troponin T STAT

Indications For Use:

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Prescription Use X 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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