AUG 2 0 2003

510(k) Summary

K031990

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 - 3723

Contact Person: Kay Taylor (for Theresa M. Ambrose)

Date Prepared: August 14, 2003

Device Name

Proprietary name: Elecsys® PreciControl Troponin T

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate Device

The Elecsys PreciControl Troponin T is substantially equivalent to the currently marketed Elecsys PreciControl Cardiac (K983492).

Device Description

The Elecsys PreciControl Troponin T is a lyophilized manufactured using recombinant human Troponin T in human serum matrix. The analyte is spiked into the matrix to the correct concentration levels.

510(k) Summary, Continued

Intended use	The Elecsys® PreciControl Troponin T is used for quality control of the Elecsys Troponin T (Cardiac T®) immunoassay on the Elecsys immunoassay system.
Comparison to predicate device	The Elecsys® PreciControl Troponin T is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® PreciControl Cardiac (K983492). The intended use of both devices are the same; as they are both intended for use as the quality control of Elecsys® immunoassays. The proposed product is a single-analyte version of the multi-analyte predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Theresa M. Ambrose, Ph.D., FACB
Regulatory Principal
Centralized Diagnostics Regulatory Submissions
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250

Re: k031990
Trade/Device Name: Elecsys® PreciControl Troponin T
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: June 25, 2003
Received: June 27, 2003

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,

Steven Gutman

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 K031990

Device Name:

Elecsys PreciControl Troponin T

Indications For Use:

PreciControl Troponin T is used for quality control of the Elecsys Troponin T (CARDIAC T) immunoassay of the Elecsys immunoassay systems.

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

(Optional Format 1-2-96)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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