K033873

FEB 13 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 Corporation
9115 Hague Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Theresa M. Ambrose

Date Prepared: December 12, 2003

Device Name

Proprietary name: Elecsys® C-Peptide CalSet

Common name: Calibrator

Classification name: Calibrator, secondary

Predicate device

The Elecsys® C-Peptide CalSet is substantially equivalent to the currently marketed Elecsys® LH CalSet II (K031299).

Device Description

The Elecsys® C-Peptide CalSet is a lyophilized product consisting of synthetic human C-Peptide in a buffered horse serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys® C-Peptide CalSet is used to calibrate the quantitative Elecsys C-Peptide assay on the Elecsys immunoassay systems.

Continued on next page

510(k) summary, continued

Comparison to predicate device

The Elecsys® C-Peptide CalSet is substantially equivalent to the currently marketed Elecsys® LH CalSet II (K031299). The below tables compare Elecsys® C-Peptide CalSet with the predicate device, Elecsys® LH CalSet II.

Similarities

Characteristic	Elecsys® C-Peptide CalSet	Predicate device Elecsys® LH CalSet II
Intended Use	For calibrating the quantitative Elecsys C-Peptide assay on the Elecsys immunoassay systems.	For calibrating the quantitative Elecsys LH assay on the Elecsys immunoassay systems.
Levels	Two	Same
Format	Lyophilized	Same
Handling	Add exactly 1.0 mL distilled water and allow to stand closed for 15 minutes to reconsititute. Mix carefully, avoiding the formation of foam.	Same

Differences

Characteristic	Elecsys® C-Peptide CalSet	Predicate device Elecsys® LH CalSet II
Matrix	Equine serum with added synthetic human C-peptide	Human serum with added human LH
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • -20 °C : 1 month (freeze only once) • On the analyzers: use only once	Unopened: • Store at 2-8°C until expiration date Reconstituted: • -20 °C : 3 months (freeze only once) • On the analyzers: use only once

Performance Characteristics

The Elecsys® C-Peptide CalSet was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 3 2004

Theresa M. Ambrose, Ph.D.
Regulatory Principal
Centralized Diagnostics Regulatory Submissions
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k033873
Trade/Device Name: Elecsys® C-Peptide CalSet
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: December 12, 2003
Received: December 15, 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,

Jean M. Cooper MS, DVM.

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 Statement

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

Device Name: Elecsys® C-Peptide CalSet

Indications For Use:

The Elecsys® C-Peptide CalSet is used for calibrating the quantitative C-Peptide assay on the Elecsys immunoassay systems.

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

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033873