SEP 2 8 1999

K992680

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 Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A Hamill

Date prepared: August 9, 1999

Predicate device

The ELECSYS® Parathyroid Hormone Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Nichols RIA test for Parathyroid Hormone (K954418).

Device Name

Proprietary name: ELECSYS® Parathyroid Hormone Test System

Common name: Parathyroid Hormone Test

Classification name: Radioimmunoassay, Parathyroid Hormone

Device description

The ELECSYS® Parathyroid Hormone Test System is based on a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined usin a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

Intended use

For the quantitative determination of parathyroid hormone in human serum and plasma.

Indication for use

For differential diagnosis of hypercalcemia and hypocalcemia.

Substantial equivalence

The ELECSYS® Parathyroid Hormone Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Nichols Intact Parathyroid Hormone (PTH) Immunoassay (K954418).

Substantial equivalence - similarities

The following table compares the ELECSYS® Parathyroid Hormone Test System, with the predicate device.

Feature	ELECSYS® Parathyroid Hormone Test System	Predicate Device
Intended use	for the quantitative determination of parathyroid hormone	for the quantitative determination of parathyroid hormone
Indication for use	For differential diagnosis of hypercalcemia and hypocalcemia.	An aid in the assessment of calcium metabolism disorders.
Sample type	Human serum and plasma	Human serum and plasma

Substantial equivalence - differences

The following table compares the ELECSYS® Parathyroid Hormone Test System, with the predicate device.

Feature	ELECSYS® Parathyroid Hormone Test System	Predicate Device
Assay principle	Electrochemiluminescence immunoassay employing the sandwich principle.	Two-site immunoradiometric assay (IRMA)
Instrument	ELECSYS® 2010 and 1010 Immunassay analyzers	Gamma counter
Measuring range	1.20-5000 pg/mL (0.127-530 pmol/L)	1.0pg/mL-highest calibrator
Expected values	15-65 pg/mL (1.6-6.9 pmol/L)	10-65 pg/mL
Traceability	Traceable to a commercially available RIA PTH test	No information in package insert
Analytical specificity	No detection of β - CrossLaps, osteocalcin, Human PTH-fragment 1-37 and bone-specific alkaline phosphatase;	No detection of Human PTH fragments 1-34, 39-68, 53-84, 44-68, and 39-84

Substantial equivalence – performance characteristics

The performance characteristics of the ELECSYS® Parathyroid Hormone Test System and the predicate device are compared in the table below.

Feature	ELECSYS® Parathyroid Hormone Test System	Predicate Device
Within-Run precision (%CV)	5.4% at 30.0 pg/mL 4.0% at 62.2 pg/mL 4.0% at 271 pg/mL 5.8% at 44.3 pg/mL 3.4% at 161 pg/mL 3.9% at 702 pg/mL	3.4% at 40 pg/mL 1.8% at 266 pg/mL
Total precision (%CV)	5.9% at 30.0 pg/mL 4.3% at 62.2 pg/mL 4.3% at 271 pg/mL 7.1% at 44.3 pg/mL 5.0% at 161 pg/mL 5.4% at 702 pg/mL	6.6% at 38 pg/mL 6.1% at 277 pg/mL
Analytical sensitivity	1.20 pg/mL	1 pg/mL

Substantial equivalence – performance characteristics, continued

The performance characteristics of the ELECSYS® Parathyroid Hormone Test System and the predicate device are compared in the table below.

Feature	ELECSYS® Parathyroid Hormone Test System	Predicate Device
Limitations	• No interference from bilirubin up to 65 mg/dL • No interference from hemoglobin up to 1.5 g/dL • No interference from intralipid up to 1500 mg/dL • No interference from biotin up to 50 ng/mL • No interference from rheumatoid factor up to 1500 U/mL • No high dose hook effect up to 17,000 U/mL	No high dose hook effect up to 100,000 pg/mL
Open vial stability	Open vial - 12 weeks (2-8° C)	Reconstituted – 6 weeks (2-8° C)
On-board stability	ELECSYS® 2010: 8 weeks ELECSYS® 1010: 4 weeks (stored alternately in refrigerator and analyzer at ambient temperature 20-25 C) Up to 20 hr. opened in total	NA
Calibration frequency	ELECSYS® 2010: • After 1 month (same lot) • after 7 days – same kit ELECSYS® 1010 • with every reagent kit • after 7 days (20-25° C) • after 3 days (25-32° C)	Assay calibrators with each run

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 28 1999

Ms. Priscilla A. Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K992680
Trade Name: ELECSYS® Parathyroid Hormone Test System
Regulatory Class: II
Product Code: CEW
Dated: August 9, 1999
Received: August 10, 1999

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~N/A~~ K992680

Device Name: **ELECSYS® Parathyroid Hormone Test System**

Indications For Use: **For the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992680

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)