JUL 2 4 2000

510(k) Summary

K 993706

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: October 28, 1999

Predicate device

The ELECSYS β-CrossLaps/serum Immunoassay is substantially equivalent to other devices marketed in the United States. We claim equivalence to the Osteometer Serum CrossLaps™ One Step ELISA (K990843).

Device name

Proprietary name	ELECSYS® β-CrossLaps/serum Immunoassay
Common name	Electrochemiluminescence Immunoassay, β-CrossLaps / Serum
Classification name	Column Chromatography & Color Development, Hydroxyproline

510(k) Summary, continued

Device description	The ELECSYS® β-CrossLaps/serum Test is based on a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using 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 card.
Intended use	Immunoassay for the in vitro quantitative determination of degradation products of type I collagen in human serum and plasma.
Indication for use	• For assessing individual bone resorption • As an aid in monitoring anti-resorptive therapies (eg. bisphosphates, hormone replacement therapy-HRT) in postmenopausal women and individuals diagnosed with ostepenia
Substantial equivalence	The ELECSYS® β-CrossLaps/serum Immunoassay is equivalent to other devices legally marketed in the United States. We claim equivalence to the Osteometer Serum CrossLaps™ One Step ELISA (K990843).

Substantial equivalence – similarities

The following table compares the ELECSYS® β-CrossLaps/serum Immunoassay with the predicate device.

Feature	ELECSYS® β-CrossLaps/serum Immunoassay	Predicate Device
Intended use	for the quantitative determination of degradation products of type I collagen	for the quantitative determination of degradation products of C-terminal telopeptides of type I collagen
Indication for use	• For assessing individual bone resorption. • As an aid in monitoring anti-resorptive therapies (bisphosphonates or hormone replacement therapy HRT) in - postmenopausal women - individuals diagnosed with osteo-penia	Diagnosis of human bone resorption as an aid in: • Monitoring bone resoprtion changes under hormone replacement therapy (HRT) or bisphosphonate therapy in - Anti-resorptive therapies in postmenopausal women - Anti-resorptive therapies in individuals diagnosed with osteopenia • Predicting skeletal response (Bone Mineral Densitiy) in postmenopausal woman undergoing anti-resorptive therapies

Substantial equivalence – similarities, continued

Feature	ELECSYS® β-CrossLaps/serum Immunoassay	Predicate Device
Specimen collection	• fasting morning blood samples are recommended • longterm investigations: samples should be always taken under the same conditions as the baseline sample	• fasting morning blood samples are recommended • longterm investigations: samples should be always taken under the same conditions as the baseline sample
Sample type	Human serum and plasma	Human serum and plasma
Antibodies	2 monoclonal antibodies against the amino-acid sequence of EKAHD-β-GGR	2 monoclonal antibodies against the amino-acid sequence of EKAHD-β-GGR

Substantial equivalence – differences

The following table compares the ELECSYS® β-CrossLaps/serum Immunoassay with the predicate device.

Feature	ELECSYS® β-CrossLaps/serum Immunoassay	Predicate Device
Assay protocol	2-step sandwich assay	1-step sandwich assay
Detection protocol	Electrochemiluminescence	ELISA/Absorbance reading
Instrument	ELECSYS® 2010 and 1010 Immunoassay Analyzers	Microtiter Plate Reader
Procedure	Automatic	Manual
Measuring range	0.010 – 6.00 ng/mL	94 – 20,000 pM
Traceability / Standardization	Internal reference standards (purified peptide): traceable by weight	No information in the package insert.

Substantial equivalence – performance characteristics

The Performance characteristics of the ELECSYS® β-CrossLaps/serum Immunoassay and the predicate device are compared in the table below.

Feature	ELECSYS® β-CrossLaps Test System	Predicate Device
Within-Rum precision (%CV)	Human sera: 4.6% at 0.08 ng/mL 1.8% at 0.39 ng/mL 1.0% at 3.59 ng/mL	Serum samples: 5.4% at 1737 pM 5.0% at 2694 pM 5.1% at 3415 pM
	Controls: 3.4% at 0.15 ng/mL 1.6% at 0.84 ng/mL 2.2% at 3.18 ng/mL	
Total precision (%CV)	Human sera: 4.7% at 0.08 ng/mL 4.3% at 0.39 ng/mL 1.6% at 3.59 ng/mL	Serum samples: 8.1% at 1963 pM 5.4% at 2820 pM 6.5% at 3503 pM
	Controls: 3.4% at 0.15 ng/mL 1.9% at 0.84 ng/mL 2.5% at 3.18 ng/mL	
Analytical sensitivity	0.01 ng/mL	94 pM

510(k) Summary, continued

Substantial equivalence – performance characteristics, continued

Feature	ELECSYS® β-CrossLaps Test System	Predicate Device
Limitations	• No interference from biliribin up to 65 mg/dL • No interference from hemoglobin up to 0.5 g/dL • No interference from intralipid up to 1500 mg/dL • No interference from biotin up to 90 ng/mL • No interference from rheumatoid factor up to 1500 U/mL • No high dose hook effect up to 150 ng/mL	• No interference from ditaurobiliribin up to 60 mg/dL • No interference from hemoglobin up to 1.0 g/dL • No interference from intralipid up to 1000 mg/dL
On-board stability	ELECSYS® 2010: 8 weeks ELECSYS® 1010: 4 weeks (stored alternately in the refrigerator and analyzer at ambient temperature 20-25°C; up to 20hr 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)	Calibration with each run

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 4 2000

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

Re: K993706
Trade Name: Elecsys® Serum β-CrossLaps/serum Immunoassay
Regulatory Class: I reserved
Product Code: JMM
Dated: June 16, 2000
Received: June 19, 2000

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.

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" (21CFR 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~~ K993706

Device Name: **ELECSYS® Serum β-CrossLaps/serum Immunoassay**

Indications For Use: **For the in vitro quantitative determination of degradation products of type I collagen in human serum and plasma, for assessing individual bone resorption. The test may be used as an aid in monitoring anti-resorptive therapies (e.g. bisphosphonates, hormone replacement therapy – HRT) in postmenopausal women and individuals diagnosed with osteopenia. The elecrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche ELECSYS 1010 and 2010 immunoassay analyzers.**

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993706

(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)