SEP 24 1999

K992981

510(k) Summary – Elecsys® Estradiol CalSet II

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: September 1, 1999

Predicate device

Roche Diagnostics Elecsys® Estradiol CalSet II is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the currently marketed Roche Diagnostics Elecsys® Estradiol CalSet.

Device description

Roche Diagnostics Elecsys® Estradiol CalSet II consists of lyophilized human serum with added estradiol in two concentration ranges.

Intended use / Indication for use

Roche Diagnostics Elecsys® Estradiol CalSet II is intended for the calibration of the quantitative estradiol assay on the Elecsys ® 1010 and 2010 immunoassay systems.

Substantial equivalence

Elecsys® Estradiol CalSet II is equivalent to other devices legally marketed in the United States. We claim equivalence to the currently marketed Roche Diagnostics Elecsys® Estradiol CalSet cleared under document K965109.

510(k) Summary – Elecsys® Estradiol CalSet II, continued

Substantial equivalence - similarities

The following table compares Elecsys® Estradiol CalSet II, with the predicate device (currently marketed modified Elecsys® Estradiol CalSet).

Comparison of Modified Device and Predicate Device

Characteristic	Elecsys® Estradiol CalSet II (Modified Device)	Elecsys® Estradiol CalSet (Predicate Device)
Intended Use	For the calibration of the quantitative estradiol assay on the Elecsys 1010 and 2010 immunoassay systems.	For the calibration of the quantitative estradiol assay on the Elecsys 1010 and 2010 immunoassay systems.
Levels	Two levels	Two levels

Substantial equivalence – differences –

Comparison of Modified Device and Predicate Device

Characteristic	Elecsys® Estradiol CalSet II (Modified Device)	Elecsys® Estradiol CalSet (Predicate Device)
Format	Lyophilized	Liquid, ready to use
Matrix	Human serum with added estradiol	Buffer/protein
Stability	• Unopened Stable at 2-8° C until expiration date • Reconstituted: ✓ -20° - 3 months ✓ On analyzer – 3 hours	• Unopened Stable at 2-8° C until expiration date • Opened ✓ 2-8° C – 12 weeks ✓ On analyzer – 5 hours

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1999

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

Re: K992981
Trade Name: Elecsys® Estradiol CalSet II
Regulatory Class: II
Product Code: JIT
Dated: September 1, 1999
Received: September 3, 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 K992981

Device Name: Elecsys® Estradiol CalSet II

Indications For Use:

For the calibration of the quantitative estradiol assay on the Elecsys 1010 and 2010 immunoassay systems.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992981

(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)