NOV 2 8 2005

K053059

510(k) Summary - Elecsys Prolactin II CalCheck

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
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3532

Contact person: Randy Johnson

Date prepared: October 28, 2005

Device name

Proprietary name: Roche Diagnostics Elecsys Prolactin II CalCheck

Common name: Calibration Verification Material

Classification name: Single (specified) Analyte Controls (Assayed and Unassayed)

Device description

The Elecsys Prolactin II CalCheck calibration verification solutions comprise three levels – low, mid and high – each with a defined Prolactin concentration range. The low solution concentration is near the lower detection limit of the assay. The mid solution is in the middle and the high solution is near the upper limit of the measuring range. Roche Diagnostics has validated that these materials are matrix compatible for use on the Elecsys systems.

Continued on next page

510(k) Summary - Elecsys Prolactin II CalCheck, Continued

Intended use

For use in the verification of the calibration established by the Elecsys Prolactin II reagent on Elecsys 1010/2010 and MODULAR ANALYTICS E170 Immunoassay analyzers.

Predicate device

The Elecsys Prolactin II CalCheck is equivalent to other devices legally marketed in the United States. We claim equivalence to the Elecsys Prolactin CalCheck (K970147).

Device comparison

The table below illustrates the similarities between the Elecsys Prolactin CalCheck (K970147) and the Elecsys Prolactin II CalCheck (modified device).

Topic	Elecsys Prolactin CalCheck (K970147)	Elecsys Prolactin II CalCheck (Modified Device)
Intended use	For use in the verification of the calibration established by the Elecsys Prolactin reagent on Elecsys® 2010 Immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Prolactin II reagent on Elecsys 1010/2010 and MODULAR ANALYTICS E170 Immunoassay analyzers.
Matrix	Human serum	Buffered equine serum
Storage form	Lyophilized	Same
Target values	Low = 500 µIU/mL Mid = 5,000 µIU/mL High = 8,000 µIU/mL	Same
Traceability	Calibrated against the WHO Standard 84/500	Same
Stability	Unopened: Up to the printed expiration date on the bottle labels at 2 - 8°C Reconstituted: 4 hours at 15 - 25°C	Unopened: Up to the printed expiration date on the bottle labels at 2 - 8°C Reconstituted: 4 hours at 15 - 25°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 8 2005

Mr. Randy Johnson, MT (ASCP)
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k053059
Trade/Device Name: Elecsys Prolactin II CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: October 28, 2005
Received: October 31, 2005

Dear Mr. Johnson:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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

510(k) Number (if known): K053059

Device Name: Elecsys Prolactin II CalCheck

Indications For Use:

For use in the verification of the calibration established by the Elecsys Prolactin II reagent on Elecsys 1010/2010 and MODULAR ANALYTICS E170 Immunoassay analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety