K012399

AUG 2 4 2001

510(k) Summary

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", 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 - 3831

Contact Person: Sherri L. Coenen

Date Prepared: July 25, 2001

Device Name

Proprietary name: FSH II CalSet

Common name: Calibrator

Classification name: Calibrator, secondary

Predicate Device

We claim substantial equivalence to the currently marketed Elecsys FSH CalSet II (K003409).

Device Description

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

510(k) Summary, Continued

Intended use

Roche Diagnostics Elecsys FSH II CalSet is used for calibrating the quantitative Elecsys FSH assay on the Elecsys 1010 and 2010 immunoassay and Modular Analytics E170 systems.

Substantial Equivalence

The table below indicates the similarities between the modified Elecsys FSH II CalSet and the predicate, Elecsys FSH CalSet II (K003409). In summary, the Elecsys FSH II CalSet described in this submission is, in our opinion, substantially equivalent to the predicate device.

Comparison of Proposed and Predicate Device

Topic	Elecsys FSH II CalSet (Proposed Device)	Elecsys FSH CalSet II (K003409)
Intended Use	Elecsys FSH II CalSet is used for calibrating the quantitative Elecsys FSH assay on the Elecsys 1010 and 2010 immunoassay and Modular Analytics E170 systems.	Elecsys FSH CalSet II is used for calibrating the quantitative Elecsys FSH assay on the Elecsys 1010 and 2010 immunoassay and Modular Analytics E170 systems.
Levels	Two levels	Two levels
Format	Lyophilized	Lyophilized
Matrix	Human serum matrix with added human FSH	Equine serum matrix with added human FSH
Stability	Unopened: • Stable at 2-8° C until expiration date Reconstituted: • -20° C for 3 months (only freeze once) • On analyzer use once only	Unopened: • Stable at 2-8° C until expiration date Reconstituted: • -20° C for 3 months (only freeze once) • On analyzer use once only

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 4 2001

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: K012399
Trade/Device Name: Elecsys FSH II CalSet
Regulation Number: 21 CFR 862.1150
Regulatory Class: II
Product Code: JIT
Dated: July 25, 2001
Received: July 27, 2001

Dear Ms. Coenen:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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,

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

Device Name: Elecsys FSH II CalSet

Indications For Use:

Elecsys FSH II CalSet is used for calibrating the quantitative Elecsys FSH assay on the Elecsys 1010 and 2010 immunoassay and Modular Analytics E170 systems.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Jessica Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012399