K060754

APR 1 2 2006

510(k) Summary - Elecsys TSH CalSet

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) 521-3544

Contact person: Kay A. Taylor

Date prepared: March 17, 2006

Device Name

Proprietary name: Elecsys TSH CalSet

Common name: Calibrator

Classification name: Calibrator, Secondary

Device description

The Elecsys TSH CalSet consists of equine serum matrix (Cal 1) and a human serum matrix with human TSH (Cal 2) in two concentration ranges. The Elecsys TSH CalSet is supplied in ready for use liquid format.

Intended use

Elecsys TSH CalSet is used for calibrating the quantitative Elecsys TSH assay on the Elecsys immunoassay analyzers.

Predicate Device

The Elecsys TSH CalSet is equivalent to other devices legally marketed in the United States. We claim equivalence to the Elecsys TSH CalSet (K961491).

Device Comparison

The table below compares the device features of the Elecsys TSH CalSet (modified) and original (K961491).

Topic	Elecsys TSH CalSet (K961491)	Elecsys TSH CalSet (Modified Device)
Intended use	Used for calibrating the quantitative Elecsys TSH assay on the Elecsys 2010 immunoassay analyzer.	Used for calibrating the quantitative Elecsys TSH assay on the Elecsys immunoassay analyzers.
Traceability	Assay standardized against the 2nd IRP WHO reference standard 80/558	Same
Levels	Two	Same
Storage Form	Liquid	Same
Matrix	Horse serum matrix with added recombinant TSH	Equine serum matrix with added TSH (human).
Stability	Unopened: o at 2-8°C up to the stated expiration date. Opened: o 4 weeks at at 2-8°C o on the analyzer up to a maximum of five hours in total.	Unopened: o at 2-8°C up to the stated expiration date. Opened: o after opening in aliquots at 2-8°C for 12 weeks. o on 1010/2010 at 20-25°C up to 5 hours o on E170 use only once.
Target Concentrations	Cal 1: 0 µIU/mL Cal 2: 1.5 µIU/mL	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 13 2006

Ms. Kay A. Taylor
Regulatory Affairs Principal
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250

Re: k060754
Trade/Device Name: Elecsys TSH CalSet
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: March 17, 2006
Received: March 21, 2006

Dear Ms. Taylor:

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): **K060754**

Device Name: **Elecsys TSH CalSet**

Indications For Use:

The Elecsys TSH CalSet is used for calibrating the quantitative Elecsys TSH assay on the Elecsys immunoassay analyzers.

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

510(k) K060754