K102157

510(k) Summary— Elecsys® PreciControl Multimarker

Introduction

In accordance with 21 CFR 807.92, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

Submitter Name, Address, Contact

Roche Diagnostics
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AUG 2 7 2010

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Date Prepared: July 29, 2010

Device name

Proprietary name: Elecsys® PreciControl Multimarker
Common name: PreciControl Multimarker
Classification: Multi-Analyte Controls, All Kinds (assayed and unassayed)

Device description

Elecsys® PreciControl Multimarker is a lyophilized product consisting of analytes in an equine serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

Predicate device

The Elecsys® PreciControl Multimarker is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys® MultiAnalyte (K033937).

Intended use

Elecsys® PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

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Device Comparison— Similarities

The table below presents the similarities between the Elecsys® PreciControl Multimarker and the predicate device, Elecsys® PreciControl MultiAnalyte (K033937).

Characteristic	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)	Elecsys® PreciControl Multimarker
Analyzer system	Elecsys and **cobas e** immunoassay analyzers	Same
Analyte concentration	• C-Peptide (ng/mL) Level 1 = 2 Level 2 = 10	Same
Format	Lyophilized	Same
Matrix	Equine serum	Same
Levels	Two	Same

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Device Comparison— Differences

The table below presents the differences between the Elecsys® PreciControl Multimarker and the predicate device, Elecsys® PreciControl MultiAnalyte (K033937).

Characteristic	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)	Elecsys® PreciControl Multimarker
Intended use	PreciControl MultiAnalyte is used for quality control of the Elecsys C-Peptide and Elecsys Insulin immunoassays on the Elecsys immunoassay systems.	Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Analyte concentration	• Insulin (µU/mL) Level 1 = 20 Level 2 = 100	• Insulin (µU/mL) Level 1 = 25 Level 2 = 80 • ACTH (pg/mL) Level 1 = 50 Level 2 = 1000 • hGH (ng/mL) Level 1 = 1.00 Level 2 = 10.0
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

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Continued

Device Comparison— Differences (continued)

The table below presents the differences between the Elecsys® PreciControl Multimarker and the predicate device, Elecsys® PreciControl MultiAnalyte (K033937).

Characteristic	Predicate Device Elecsys® PreciControl MultiAnalyte (K033937)	Elecsys® PreciControl Multimarker
Stability	Unopened : Store at 2-8°C until expiration date Reconstituted: • on the analyzer at 20-25°C: up to 3 hrs • at -20°C: 3 months (freeze only once) After Thawing: use only once.	Unopened : Store at 2-8°C until expiration date Reconstituted: • on the analyzer at 20-25 °C: up to 5 hrs • at -20°C: 31 days (freeze only once) • or at 2-8°C for 72 hours

Performance Characteristics

The Elecsys® PreciControl Multimarker was evaluated for value assignment, stability, and duration of reconstitution.

Conclusion

The data demonstrate that the performance of the Elecsys® PreciControl Multimarker is substantially equivalent to that of the predicate device, Elecsys® PreciControl MultiAnalyte (K033937).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 27 2010

Re: k102157
Trade/Device Name: Elecsys PreciControl Multimarker
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: July 29, 2010
Received: July 30, 2010

Dear Ms. Baumann:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102157

Indications for Use Form

510(k) Number (if known): K102157

Device Name: Elecsys PreciControl Multimarker

Indications for Use: Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

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

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

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

Doug Rhenheimer

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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