K111506

510(k) Summary— Elecsys® PreciControl Varia 3

JUL - 8 2011

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

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Date Prepared: May 31, 2011

Device name

Proprietary name: Elecsys® PreciControl Varia 3
Common name: PreciControl Varia 3
Classification: Multi-Analyte Controls, All Kinds (assayed and unassayed)

Device description

Elecsys® PreciControl Varia 3 is a lyophilized product consisting of analytes in a human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

Predicate devices

Elecsys® PreciControl Varia 3 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys® PreciControl Anemia (K082340) and Elecsys® PreciControl Bone (K051543).

Elecsys® PreciControl Varia 3 is a multi-analyte control that combines the analytes in the Elecsys® PreciControl Anemia (K082340) and Elecsys® PreciControl Bone (K051543) multi-analyte controls.

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Intended use

Elecsys® PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Device Comparison—Similarities

Elecsys® PreciControl Varia 3 is a multi-analyte control that combines the analytes in the Elecsys® PreciControl Anemia (K082340) and Elecsys® PreciControl Bone (K051543) multi-analyte controls.

Tables 1 and 2 below present the similarities between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 1) and Elecsys® PreciControl Bone (K051543, Table 2).

Table 1. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Anemia)—Similarities

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Anemia (K082340)
Analyzer system	Elecsys and **cobas e** immunoassay analyzers	Same
Format	Lyophilized	Same
Matrix	Human serum	Same
Levels	Three	Same
Traceability	• Vitamin B_{12}—Commercially available radio-binding assay • Ferritin—NIBSC Standard 80/602 • Folate—Elecsys Folate II Assay	Same

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Device Comparison—Similarities (continued)

Tables 1 and 2 present the similarities between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 1) and Elecsys® PreciControl Bone (K051543, Table 2).

Table 2. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Bone)—Similarities

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Bone (K051543)
Analyzer system	Elecsys and **cobas e** immunoassay analyzers	Same
Format	Lyophilized	Same
Levels	Three	Same
Traceability	• β-CrossLaps/serum (β-CTx)—Gravimetry • Osteocalcin—In-house reference system (commercially available osteocalcin immuno/radio-binding assay • Parathyroid Hormone (PTH and PTH STAT)—In-house reference system (commercially available PTH radio-binding assay)	Same

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Device Comparison—Differences

Elecsys® PreciControl Varia 3 is a multi-analyte control that combines the analytes in the Elecsys® PreciControl Anemia (K082340) and Elecsys® PreciControl Bone (K051543) multi-analyte controls.

Tables 3 and 4 below present the differences between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 3) and Elecsys® PreciControl Bone (K051543, Table 4).

Table 3. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Anemia)—Differences

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Anemia (K082340)
Intended use	Elecsys PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Anemia is used for quality control of Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Analyte concentration	• Ferritin (ng/mL) Level 0 = 14 Level 1 = 150 Level 2 = 1000 • Folate (ng/mL) Level 0 = N/A Level 1 = 3.9 Level 2 = 12 • Vitamin B_{12} (pg/mL) Level 0 = 230 Level 1 = 500 Level 2 = 1000	• Ferritin (ng/mL) Level 1 = 15 Level 2 = 500 Level 3 = 1500 • Folate (ng/mL) Level 1 = 3 Level 2 = 8 Level 3 = 14 • Vitamin B_{12} (pg/mL) Level 1 = 350 Level 2 = 700 Level 3 = 1500
Handling	Dissolve carefully the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 30 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.
Volume (reconstituted)	3.0 mL	2.0 mL

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Device Comparison— Differences (continued)

Tables 3 and 4 present the differences between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 3) and Elecsys® PreciControl Bone (K051543, Table 4).

Table 3. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Anemia)—Differences, continued

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Anemia (K082340)
Stability	Unopened at 2 – 8 °C: up to the stated expiration date Reconstituted/thawed serum: o at – 20 °C: 31 days (freeze only once) o at 2 – 8 °C: 72 hours o at 20 – 25 °C on-board the analyzers: up to 5 hours	Unopened at 2 – 8 °C: up to the stated expiration date Reconstituted serum: o at – 20 °C: 1 month (freeze only once) o at 2 – 8 °C: 3 days o at 20 – 25 °C on-board the analyzers: up to 5 hours o at 20 – 25 °C: up to 8 hours o after thawing: use only once

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Device Comparison—Differences (continued)

Tables 3 and 4 present the differences between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 3) and Elecsys® PreciControl Bone (K051543, Table 4).

Table 4. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Bone)—Differences

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Bone (K051543)
Intended use	Elecsys PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Bone is used for quality control of Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Analyte concentration	• β-CTx (pg/mL) Level 0 = N/A Level 1 = 320 Level 2 = 750 • Osteocalcin (ng/mL) Level 0 = N/A Level 1 = 20 Level 2 = 100 • PTH (pg/mL) Level 0 = 25 Level 1 = 60 Level 2 = 200	• β-CTx (pg/mL) Level 1 = 315 Level 2 = 750 Level 3 = 3000 • Osteocalcin (ng/mL) Level 1 = 20 Level 2 = 100 Level 3 = 205 • PTH (pg/mL) Level 1 = 60 Level 2 = 205 Level 3 = 850
Handling	Dissolve carefully the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 30 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 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

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510(k) Summary— Elecsys® PreciControl Varia 3, Continued

Device Comparison— Differences (continued)

Tables 3 and 4 present the differences between Elecsys® PreciControl Varia 3 and the predicate devices, Elecsys® PreciControl Anemia (K082340, Table 3) and Elecsys® PreciControl Bone (K051543, Table 4).

Table 4. Comparison of Candidate (Elecsys® PreciControl Varia 3) and Predicate (Elecsys® PreciControl Bone)—Differences, continued

Characteristic	Candidate Device Elecsys® PreciControl Varia 3	Predicate Device Elecsys® PreciControl Bone (K051543)
Volume (reconstituted)	3.0 mL	2.0 mL
Stability	Unopened at 2 – 8 °C: up to the stated expiration date Reconstituted/thawed serum: o at – 20 °C: 31 days (freeze only once) o at 2 – 8 °C: 72 hours o at 20 – 25 °C on-board the analyzers: up to 5 hours	Unopened at 2 – 8 °C: up to the stated expiration date Reconstituted/thawed serum: o at – 20 °C: 1 month (4 freeze/thaw cycles possible) o at 2 – 8 °C: 5 days o at 20 – 25 °C: up to 8 hours

Performance Characteristics

Elecsys® PreciControl Varia 3 was evaluated for value assignment, stability, and duration of reconstitution.

Conclusion

The data demonstrate that the performance of Elecsys® PreciControl Varia 3 is substantially equivalent to that of the predicate devices, Elecsys® PreciControl Anemia (K082340) and Elecsys® PreciControl Bone (K051543).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 08 2011

Roche Diagnostics
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Re: k111506
Trade Name: Elecsys PreciControl Varia 3
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: May 31, 2011
Received: June 1, 2011

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 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); 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).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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

Indications for Use Form

510(k) Number (if known): K111506

Device Name: Elecsys® PreciControl Varia 3

Indications for Use:

Elecsys® PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers. See the package insert for the list of all analytes claimed.

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)

Carol C Benson

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

510(k) K110506