



Food and Drug Administration  
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Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

ROCHE DIAGNOSTICS  
PATTY BATES  
REGULATORY AFFAIRS PRINCIPAL  
9115 HAGUE ROAD  
INDIANAPOLIS IN 46250

October 2, 2015

Re: K152526  
Trade/Device Name: Elecsys Progesterone III Calset  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: II  
Product Code: JIT  
Dated: September 2, 2015  
Received: September 3, 2015

Dear Ms. Bates:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Katherine Serrano -S**

For: Courtney H. Lias  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

k152526

Device Name

Elecsys Progesterone III CalSet

Indications for Use (Describe)

Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone III assay on the Elecsys and cobas e immunoassay analyzers.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary, Elecsys Progesterone III CalSet

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**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.

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**Submitter Name, Address, Contact Information** Roche Diagnostics Corporation  
9115 Hague Road, P.O. Box 50416  
Indianapolis, IN 46250-0416

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Email: adam.clark@roche.com

Date Prepared: September 2, 2015

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**Device Name** Proprietary name: Elecsys Progesterone III CalSet

Common name: Progesterone III CalSet

Classification: 21 CFR 862.1150, Calibrator, Secondary

Product Code: JIT

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**Establishment Registration** For the Progesterone III CalSet, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany, is 9610126 and for Penzberg, Germany, is 9610529. The establishment registration number for Roche Diagnostics United States is 1823260.

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**Classification** FDA has classified the product as a Class II device.

<b>Product Name</b>	<b>Panel</b>	<b>Product Code</b>	<b>Classification Name</b>	<b>Regulation Citation</b>
Progesterone III CalSet	Clinical Chemistry	JIT	Calibrator, Secondary	21 CFR 862.1150

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## 510(k) Summary, Elecsys Progesterone III CalSet, *continued*

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**Device Description** Elecsys Progesterone III CalSet:

- The Elecsys Progesterone III CalSet is a lyophilized product consisting of plant-derived progesterone in a human serum matrix. It is traceable via ID-GC/MS (isotope dilution gas chromatography/mass spectrometry) to highly purified progesterone by weight analogous to BCR-348R and ERM-DA347.

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**Intended use** Elecsys Progesterone III CalSet:

- The Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone III assay on the Elecsys and **cobas e** immunoassay analyzers.

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**Predicate device** The Elecsys Progesterone III CalSet is substantially equivalent to the predicate device, Elecsys Progesterone II CalSet (K964841).

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**Substantial Equivalence Comparison** The following table compare the Elecsys Progesterone III CalSet with the predicate device.

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## 510(k) Summary, Elecsys Progesterone III CalSet, *continued*

**Comparison Table** The table below compares Elecsys Progesterone III CalSet with the predicate device, Elecsys Progesterone II CalSet (K964841).

The change in the new product is the addition of calibrator stability at -20°C.

**Table**

<b>Characteristic</b>	<b>Elecsys Progesterone III CalSet (Candidate)</b>	<b>Elecsys Progesterone II CalSet (Predicate) (K964841)</b>
Intended Use	Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone III assay on the Elecsys and <b>cobas e</b> immunoassay analyzers.	Progesterone II CalSet is used for calibrating the quantitative Elecsys Progesterone assay on the Elecsys and <b>cobas e</b> immunoassay analyzers.
Analyte	Progesterone (plant-derived)	Same
Matrix	Human serum matrix	Same
Levels	Two	Same
Target Values	Cal 1: 0.080 ng/mL Cal 2: 53 ng/mL	Same
Format	Lyophilized	Same
Handling	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the foam formation. Transfer aliquots of the reconstituted calibrators into empty labeled snap-cap bottles (CalSet Vials). Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20°C. Perform only one calibration procedure per aliquot.	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the foam formation. Transfer aliquots of the reconstituted calibrators into empty labeled snap-cap bottles (CalSet Vials). Attach the supplied labels to the additional bottles. Store the aliquots at 2-8°C for later use. Perform only one calibration procedure per aliquot.

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## 510(k) Summary, Elecsys Progesterone III CalSet, *continued*

Table *continued*

Characteristic	Elecsys Progesterone III CalSet (Candidate)	Elecsys Progesterone II CalSet (Predicate) (K964841)
Stability	<p><u>Unopened:</u></p> <ul style="list-style-type: none"> <li>Store at 2-8°C until expiration date</li> </ul> <p><u>Opened:</u></p> <ul style="list-style-type: none"> <li>2-8°C: 24 hours</li> <li>20-25°C on the analyzer: use only once</li> <li>-20°C: 31 days (freeze only once)</li> </ul>	<p><u>Unopened:</u></p> <ul style="list-style-type: none"> <li>Store at 2-8°C until expiration date</li> </ul> <p><u>Opened:</u></p> <ul style="list-style-type: none"> <li>2-8°C: 12 weeks</li> <li>20-25°C on the analyzer: use only once</li> </ul>

**Traceability** The Elecsys Progesterone III CalSet is traceable via ID-GC/MS (isotope dilution gas chromatography/mass spectrometry) to highly purified progesterone by weight analogous to BCR-348R and ERM-DA347.

**Evaluations Summary** The Elecsys Progesterone III CalSet was evaluated for value assignment, reconstitution and stability.

**CalSet Value Assignment** Value assignment testing was conducted and passed pre-defined acceptance criteria. The target values for the two levels of the Progesterone III CalSet kit are chosen to obtain the best fit with the Master Calibration Curve, together with the Rodbard curve parameters encoded in the reagent barcode. For each Elecsys Progesterone III CalSet lot manufactured, the calibrators are run in duplicate on at least three (3) **cobas e 411** analyzers and at least three (3) **cobas e 601/MODULAR ANALYTICS E170** analyzers with all Progesterone III reagent lots available. The assigned value of each calibrator is defined as the median value obtained over at least six (6) runs on at least three (3) analyzers) of the respective calibrator.

Measurement values for PreciControl Universal (Level 1 & 2) are read off from the calibration curves generated. The PreciControl Universal is a multi-analyte control recommended for use with specified analytes. The controls are used for monitoring accuracy and precision of the specified assays. The pre-defined acceptance criteria for PreciControl Universal have to be met to release the Assigned Values for Progesterone III CalSet.

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## 510(k) Summary, Elecsys Progesterone III CalSet, *continued*

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### **Stability Studies**

Three studies were performed in order to verify the stability claims for the Progesterone III CalSet. Stability studies after reconstitution and an accelerated stability study were completed on the **cobas e 411**. Additionally, a real-time stability study is planned.

#### **Study 1. Stability at 2-8°C, -20°C, in open vial and freeze/thaw cycles (after reconstitution):**

The on-test materials were reconstituted and stored closed for 25 hours at 2 to 8°C, and for 32 days at -20°C and for 3 hours at 20 to 25°C in open vial prior to testing. In addition, the stability of the Progesterone III CalSet for two (2) freeze/thaw cycles was evaluated.

The on-test and reference materials were tested in duplicate and the recovery was calculated as percent of the reference value.

The acceptance criterion was 95 to 105 % signal recovery of the reference material value. The reference material was a freshly reconstituted set of Progesterone III CalSet.

#### **Study 2. Accelerated Stability:**

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was a freshly reconstituted set of Progesterone III CalSet (stored at 2 to 8°C). After 3 weeks, the on-test and reference materials were tested in duplicate. The on-test recovery was calculated as a percent of the reference value. One Progesterone III CalSet lot was evaluated in duplicate.

The acceptance criterion was 95 to 105 % recovery of the reference material value.

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## 510(k) Summary, Elecsys Progesterone III CalSet, *continued*

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### **Stability Studies,** *continued*

#### **Study 3. Real-Time Stability:**

In addition, real-time stability is being evaluated as follows:

In the on-going real-time stability study, the Progesterone III CalSet test material is stored at 2-8°C. The CalSets are tested in duplicate at specified intervals over the shelf life of the device up to the planned shelf life plus one month (19 months).

Real-time stability is calculated based on the recovery of signal of stressed calibrator (stored at 2-8°C) vs. unstressed calibrator (stored at -20°C). At the specified intervals over the shelf life, the mean value of the stressed calibrator was calculated as percent recovery of the unstressed value (each tested in duplicates at the same time point).

The acceptance criterion for Progesterone III Calibrator 1 and 2 is recovery of 95-105 % of the reference value.

The testing will continue with this stability protocol until data to support a claim of 18 months is achieved.

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### **Conclusion**

We trust that the information provided in this Premarket Notification (510(k)) will support a determination of substantial equivalence for the Elecsys Progesterone III CalSet.