March 22, 2024

Amy Pierce
Regulatory Affairs Project Manager
9115 Hague Rd.
P.O. Box 50416
Indianapolis, Indiana 46250

Re: K231927
Trade/Device Name: Elecsys PTH, Elecsys PTH STAT
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid Hormone Test System
Regulatory Class: Class II
Product Code: CEW
Dated: February 22, 2024
Received: February 22, 2024

Dear Amy Pierce:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231927

Device Name
Elecsys PTH and Elecsys PTH STAT

Indications for Use *(Describe)*
Elecsys PTH and Elecsys PTH STAT:

Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Elecsys PTH and Elecsys PTH STAT
510(k) Summary for K231927

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

In accordance with 21 CFR 807.87, 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).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the Elecsys PTH and Elecsys PTH STAT.

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Amy Pierce Phone: (317) 440-5108 Email: amy.pierce.ap2@roche.com
Date Prepared	March 11, 2024
Proprietary Name	Elecsys PTH Elecsys PTH STAT
Common Name	Parathyroid hormone test system
Classification Name	Radioimmunoassay, Parathyroid Hormone
Product Codes, Regulation Numbers	CEW, 21 CFR 862. 1545
Predicate Devices	Roche Diagnostics Elecsys PTH and Elecsys PTH STAT (K070709)
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmBH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260.

1. DEVICE DESCRIPTION

Both the Elecsys PTH and Elecsys PTH STAT immunoassays make use of a sandwich test principle using a biotinylated monoclonal PTH-specific antibody labeled with a ruthenium complex. Both the Elecsys PTH and Elecsys PTH STAT immunoassays are intended for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. These assays can be used intraoperatively. They are intended for use on the cobas e immunoassay analyzers.

Results are determined via a calibration curve which is instrument-specifically generated by a two-point calibration and a master curve provided via the reagent barcode.

The reagent working solutions include: Rack Pack (kit placed on the analyzer)

- M Streptavidin coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin coated microparticles 0.72 mg/mL; preservative.
- R1 Anti PTH Ab~biotin (gray cap), 1 bottle, 7 mL: Biotinylated monoclonal anti PTH antibody (mouse) 2.3 mg/L; phosphate buffer 100 mmol/L, pH 7.0; preservative.
- R2 Anti PTH Ab~Ru(bpy) (black cap), 1 bottle, 7 mL: Monoclonal anti PTH antibody (mouse) labeled with ruthenium complex 2.0 mg/L; phosphate buffer 100 mmol/L, pH 7.0; preservative.

2. INDICATIONS FOR USE

The following Indications for Use is applicable to both Elecsys PTH and Elecsys PTH STAT:

Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

3. TECHNOLOGICAL CHARACTERISTICS

Table 1 compares Elecsys PTH (biotin update) with its predicate device, Elecsys PTH (K070709). Table 2 compares Elecsys PTH STAT (biotin update) with its predicate device, Elecsys PTH STAT (K070709).

Table 1: Technical Characteristics Comparison Table between Elecsys PTH (biotin update) and Elecsys PTH

Feature	Candidate Device Elecsys PTH	Predicate Device Elecsys PTH (K070709)
Intended Use	Elecsys PTH is intended for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers	Elecsys PTH is intended for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers
Assay Method	Sandwich	Same
Detection Method	Electrochemiluminescence "ECLIA"	Same
Applications/Test Time	18 minute	Same
Sample Type/Matrix	Human serum/Plasma	Same
Sample Anticoagulants	K_2-EDTA/K_3-EDTA	Same
Handling of R1 and R2	Liquid, ready to use	Same
Buffer composition R1	Phosphate buffer	Same
Calibrator	PTH CalSet	Same
Calibration Method	2-point calibration	Same

Feature	Candidate Device Elecsys PTH	Predicate Device Elecsys PTH (K070709)
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Calibration interval may be extended based on acceptable verification of calibration by the laboratory. Renewed calibration is recommended as follows: • after 12 weeks when using the same reagent lot • after 7 days (when using the same reagent kit on the analyzer) • as required: e.g. quality control findings outside the defined limits	Same
Controls	PreciControl Varia	Same
Traceability/Standardization	Standardized against a commercial PTH test (RIA).	Same
Reagent Stability	Reagent stability for on analyzer is now 28 days.	• unopened at 2-8 °C: up to the stated expiration date • after opening at 2-8 °C: 12 weeks • on analyzers: 8 weeks
Measuring Range	1.20-5,000 pg/mL	6-5,000 pg/mL
Biotin Tolerance	Up to 1200 ng/mL	Up to 50 ng/mL

Table 2: PTH STAT vs PTH STAT

Feature	Candidate Device Elecsys PTH STAT	Predicate Device Elecsys PTH STAT(K070709)
Intended Use	Elecsys PTH STAT is intended for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers	Elecsys PTH STAT is intended for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers

Feature	Candidate Device Elecsys PTH STAT	Predicate Device Elecsys PTH STAT(K070709)
Assay Method	Sandwich	Same
Detection Method	Electrochemiluminescence "ECLIA"	Same
Applications/Test Time	9 minute	Same
Sample Type/Matrix	Human serum/Plasma	Same
Sample Anticoagulants	K_2-EDTA/K_3-EDTA	Same
Handling of R1 and R2	Liquid, ready to use	Same
Buffer composition R1	Phosphate buffer	Same
Calibrator	PTH STAT CalSet	Same
Calibration Method	2-point calibration	Same
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Calibration interval may be extended based on acceptable verification of calibration by the laboratory. Renewed calibration is recommended as follows: • after 12 weeks when using the same reagent lot • after 7 days (when using the same reagent kit on the analyzer) • as required: e.g. quality control findings outside the defined limits	Same
Controls	PreciControl Varia	Same
Traceability/Standardization	Standardized against a commercial PTH test (RIA).	Same
Reagent Stability	Reagent stability for on analyzer is now 28 days.	• unopened at 2-8 °C: up to the stated expiration date • after opening at 2-8 °C: 12 weeks • on analyzers: 8 weeks
Measuring Range	1.20-5,000 pg/mL	6-5,000 pg/mL
Biotin Tolerance	Up to 1200 ng/mL	Up to 50 ng/mL

4. NON-CLINICAL PERFORMANCE EVALUATION

The following performance data are provided in support of the substantial equivalence determination. All performance specifications were met.

4.1. Precision

4.1.1. Repeatability and Intermediate Precision

Precision measurement were conducted for the updated Elecsys PTH and Elecsys PTH STAT assays to evaluate repeatability (within-run precision) and intermediate precision (within-laboratory precision) according to CLSI EP05-A3. All samples met the predefined acceptance criteria.

Elecsys PTH Precision

cobas e 601 analyzer					
		Repeatability		**Intermediate precision**	
Sample	Mean	SD	CV	SD	CV
	pg/mL	pg/mL	%	pg/mL	%
HS[b)] 1	9.29	0.195	2.1	0.404	4.4
HS 2	13.8	0.210	1.5	0.420	3.0
HS 3	54.6	0.444	0.8	0.798	1.5
HS 4	2467	17.7	0.7	32.6	1.3
HS 5	4514	41.2	0.9	49.1	1.1
PC[c)] Varia 0	24.5	0.291	1.2	0.540	2.2
PC Varia 1	58.0	0.545	0.9	1.20	2.1
PC Varia 2	175	1.59	0.9	2.56	1.5

Elecsys PTH STAT Precision

cobas e 601 analyzer					
		Repeatability		**Intermediate precision**	
Sample	Mean	SD	CV	SD	CV
	pg/mL	pg/mL	%	pg/mL	%
HS[b)] 1	9.27	0.224	2.4	0.409	4.4
HS 2	14.0	0.236	1.7	0.386	2.8
HS 3	54.0	0.565	1.0	0.887	1.6
HS 4	2399	14.0	0.6	36.8	1.5
HS 5	4390	34.9	0.8	49.0	1.1
PC[c)] Varia 0	22.3	0.292	1.3	0.515	2.3
PC Varia 1	49.9	0.534	1.1	1.07	2.1
PC Varia 2	151	1.10	0.7	2.58	1.7

4.1.2. Reproducibility

Lot-to-lot reproducibility was performed for both the Elecsys PTH and Elecsys PTH STAT assay using three reagent lots according to CLSI EP05-A3. All predefined acceptance criteria was met for the lot-to-lot reproducibility experiment.

4.2. Analytical Sensitivity

4.2.1. Limit of Blank (LoB)

The Limit of Blank (LoB) was determined according to CLSI EP17-A2. The LoB claim in the labeling will be set to 1.2 pg/mL.

4.2.2. Limit of Detection (LoD)

The Limit of Detection (LoD) was determined according to CLSI EP17-A2. The LoD claim in the labeling will be set to 2.4 pg/mL.

4.2.3. Limit of Quantitation (LoQ)

The Limit of Quantitation (LoQ) was determined according to CLSI EP17-A2. The LoQ claim in the labeling will be set to 6 pg/mL.

4.3. Linearity/Assay Reportable Range

Linearity was evaluated according to CLSI EP06-Ed2 with the Elecsys PTH and Elecsys PTH STAT assays on one cobas e 601 analyzer. The dilution series contained a minimum of 9 concentrations throughout the measuring range. A measuring range of 6-5000 pg/mL will be claimed in the labeling.

4.4. High Dose Hook Effect

The high-dose hook effect (HDHE) of the Elecsys PTH and Elecsys PTH STAT assays was assessed on one cobas e 601 analyzer using a dilution series. No hook effect was seen up to 17000 pg/mL.

4.5. Human Anti-Mouse Antibodies (HAMA)

The effect of the presence of human anti-mouse antibodies (HAMA) on the Elecsys PTH assay was assessed on one cobas e 601 analyzer.

4.6. Endogenous Interferences

Nine endogenous substances were evaluated for potential interference with Elecsys PTH and Elecsys PTH STAT on the **cobas e** 601 analyzer. All predefined acceptance criteria were met, and the proposed labeling claims for each endogenous substance can be found below (applicable to both Elecsys PTH and Elecsys PTH STAT:

Compound	**Concentration tested**
Bilirubin	≤ 1129 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.155 mmol/L or ≤ 250 mg/dL
Intralipid	≤ 1500 mg/dL
Biotin	≤ 4920 nmol/L or ≤ 1200 ng/mL
Rheumatoid Factor	≤ 1200 IU/mL

Compound	Concentration tested
Serum Albumin	≤ 7.0 g/dL
Human IgG	≤ 1.4 g/dL
Human IgM	≤ 0.2 g/dL
Human IgA	≤ 0.48 g/dL

4.7. Analytical Specificity/Cross-Reactivity

A cross-reactivity study was conducted with Elecsys PTH and Elecsys PTH STAT on the cobas e 601 analyzer to evaluate the potential cross-reacting compounds using human serum samples. Samples were measured in the presence and absence of the potential cross-reactants and cross-reactivity was calculated. No cross reactivities were found for: PTH fragment 1-34, PTH fragment 1-37 and PTH related protein (1-86). The assay has a 96 % cross-reactivity to the PTH fragment 7-84.

4.8. Exogenous Interferences – Drugs

An exogenous interference study was conducted to evaluate 17 commonly and four specially used pharmaceutical compounds for potential interference with Elecsys PTH and Elecsys PTH STAT assays on the **cobas e** 601 analyzer. The predefined acceptance criteria was met for all drugs tested, and no interference was observed.

4.9. Sample Matrix Comparison

The effect on quantitation of analyte in the presence of anticoagulants with Elecsys PTH and Elecsys PTH STAT immunoassays was determined by comparing values obtained from samples drawn into serum, K2- and K3-EDTA plasma primary tubes. The specifications were fulfilled and thus the resulting data support the package-insert claim that K2-EDTA and K3-EDTA plasma are acceptable sample types.

4.10. Method Comparison to Predicate

A method comparison study was performed in concordance with the CLSI guideline EP09-A3 using the Elecsys PTH biotin updated assay and the current Elecsys PTH assay. A method comparison study was also performed using the Elecsys PTH STAT biotin updated assay and the current Elecsys PTH STAT assay. Samples span the measuring range. The results can be found below:

Elecsys PTH Method Comparison

The sample concentrations were between 6.16 and 4751 pg/mL for 257 samples.

Passing/Bablok	Linear regression
y = 0.966x + 0.411	y = 0.968x + 0.272
τ = 0.990	r = 1.000

Elecsys PTH STAT Method Comparison

The concentrations were between 10.3 and 4532 pg/mL for 216 samples.

Passing/Bablok	Linear regression
y = 0.981x -1.133	y = 0.982x -1.228
τ = 0.991	r = 1.000

4.11. Stability

Stability studies were conducted for Elecsys PTH and Elecsys PTH STAT and met the predefined acceptance criteria. Stability data below are applicable to both Elecsys PTH and Elecsys PTH STAT.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on the analyzer	28 days

5. REFERENCE RANGE STUDY

A multi-site study was performed to determine the reference range for the Elecsys PTH and Elecsys PTH STAT assay with 490 apparently healthy adult samples in the United States. The reference range was determined to be 17.9 58.6 pg/mL (2.5th 97.5th percentiles).

6. ADDITIONAL INFORMATION

Elecsys PTH and Elecsys PTH STAT are intended to be used with the following calibrators and controls:

- CalSet PTH (for use with Elecsys PTH)
- CalSet PTH STAT (for use with Elecsys PTH STAT)
- PreciControl Varia (for use with both Elecsys PTH and Elecsys PTH STAT)

There have been no changes to these items marketed with the new Elecsys PTH and Elecsys PTH STAT assays.

7. CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports the determination that the Elecsys PTH immunoassay (updated material number 08928380160) is substantially equivalent to the predicate device, Elecsys PTH system (current assay, material number 11972103160). The information also supports the determination that the Elecsys PTH STAT immunoassay (updated material number 08928410160) is substantially equivalent to the predicate device, Elecsys PTH STAT system (current assay, material number 04892470160).