April 24, 2026

Roche Diagnostics GmbH
Eva Jad
Regulatory Affairs Project Manager
Sandhofer Strasse 116
68305 Mannheim
Germany

Re: K252431
Trade/Device Name: Elecsys Calcitonin
Regulation Number: 21 CFR 862.1140
Regulation Name: Calcitonin Test System
Regulatory Class: Class II
Product Code: JKR
Dated: March 19, 2026
Received: March 19, 2026

Dear Eva Jad:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k252431

Device Name
Elecsys Calcitonin

Indications for Use *(Describe)*
The Calcitonin immunoassay is intended for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings.
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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510k Summary
Elecsys Calcitonin (K252431)

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 Traditional 510(k) Premarket Notification.

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

Submitter Name:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim, Germany
Contact:	Eva Jad Phone: 0049 1525 4993906 Email: eva.jad@roche.com
Date Prepared:	April 24, 2026
Proprietary Name:	Elecsys Calcitonin
Common Name:	Calcitonin test system
Classification Name:	Radioimmunoassay, Calcitonin
Product Code:	JKR
Regulation Number:	21 CFR 862.1140
Predicate Device:	Elecsys Calcitonin (K132828)
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmbH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260

1. DEVICE DESCRIPTION

The Elecsys Calcitonin assay is a sandwich principle assay with a total duration of 18 minutes including the following steps:

1st incubation: 50 µL of sample, a biotinylated monoclonal hCT-specific antibody and a monoclonal hCT-specific antibody labeled with a ruthenium complex react to form a sandwich complex.

2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin

The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

The Elecsys Calcitonin reagents “M”, “R1” and “R2” are combined in the so-called “rackpack”, a bundle of the three reagent bottles, which is placed on the instrument as a single unit. The reagent rackpack is labeled as hCT.

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-hCT-Ab~biotin (gray cap), 1 bottle, 8 mL: Biotinylated monoclonal anti-hCT antibody (mouse) 1.50 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative.

R2 Anti-hCT-Ab~Ru(bpy)2+3 (black cap), 1 bottle, 8 mL: Monoclonal anti-hCT antibody (mouse) labeled with ruthenium complex 1.0 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative.

2. INDICATIONS FOR USE

The Calcitonin immunoassay is intended for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas** e immunoassay analyzers.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the updated Elecsys Calcitonin assay with its predicate device, the current Elecsys Calcitonin assay (K132828).

Table: Comparison Table of the Current Elecsys Calcitonin and Updated Elecsys Calcitonin Assay)

Item	Elecsys Calcitonin (current assay design, K132828)	Elecsys Calcitonin (updated assay design)
Proprietary name	Elecsys Calcitonin	No change
Intended Use	Immunoassay for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.	No change
Test format	Sandwich principle	No change
Test type	Quantitative	No change
Application time	18 min	No change
Handling of R1 and R2	Liquid, ready to use	No change
Biotin tolerance	≤ 40 ng/mL	≤ 1200 ng/mL
Measuring range	1 - 2000 pg/mL	No change

Item	Elecsys Calcitonin (current assay design, K132828)	Elecsys Calcitonin (updated assay design)
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: cobas e 411 analyzers: - After 8 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	No change
Controls	PreciControl Varia	No change
Traceability/ Standardization	Standardized to IRP WHO Reference Standard 89/620.	No change

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 was evaluated with five human serum samples and two levels of control by testing two replicates per run, two runs per day for 21 days, on a **cobas e** 411 analyzer. Repeatability and Intermediate precision were calculated according to CLSI EP05-A3. All data met the predefined acceptance criteria.

cobas e 411 analyzer					
		Repeatability		**Intermediate precision**	
Sample	Mean pg/mL	SD pg/mL	CV %	SD pg/mL	CV %
Human serum 1	1.02	0.080	7.9	0.120	11.8
Human serum 2	10.2	0.261	2.5	0.466	4.6
Human serum 3	62.1	1.91	3.1	2.95	4.7

cobas e 411 analyzer					
		Repeatability		**Intermediate precision**	
Sample	Mean pg/mL	SD pg/mL	CV %	SD pg/mL	CV %
Human serum 4	905	21.8	2.4	41.3	4.6
Human serum 5	1882	83.0	4.4	107	5.7
PreciControl Varia 1	9.35	0.197	2.1	0.391	4.2
PreciControl Varia 2	84.5	1.93	2.3	3.23	3.8

4.1.2. Reproducibility

A multi-site-multi-lot reproducibility experiment was performed using repeated measurements of seven concentration levels containing five human serum pools and two control levels according to CLSI EP05-A3. Data were collected at two external sites and one internal site using three commercial reagent lots of the updated assay. All data met the predefined acceptance criteria.

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 0.3 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 0.5 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 1 pg/mL.

4.3. Linearity/Assay Reportable Range

Linearity was evaluated on the **cobas e** 411 analyzer according to CLSI EP06-Ed2. The dilution series contained a minimum of seven concentrations throughout the measuring range. A measuring range of 1 to 2000 pg/mL will be claimed in the labeling.

4.4. Dilution Study

Dilution Testing was performed according to CSLI EP34. The recommended dilution is 1:100., either automatically by the analyzer or manually.

4.5. Sample Matrix Comparison

The effect on quantitation of analyte in the presence of anticoagulants with the Elecsys Calcitonin assay was determined by comparing values obtained from samples drawn into Serum, Li-Heparin, K2-and K3-EDTA plasma primary tubes. Also tubes with separating gel for both serum (SST) and plasma (Li-PST) were tested. The specifications were fulfilled and thus the resulting data support the package-insert claims.

4.6. Human Anti-Mouse Antibodies (HAMA)

The effect of the presence of human anti-mouse antibodies (HAMA) was assessed on the **cobas e** 411 analyzer. Interference was tested at low, medium and high concentrations of Calcitonin. The Elecsys Calcitonin assay is affected by HAMA interference at high HAMA levels.

Internal Study data show, for HAMA levels of 805 ng/mL, at calcitonin concentrations above 18 pg/mL, negative biases up to 20% have been observed. Less than ±10% bias was observed with HAMA levels of 81 ng/mL.

In rare cases when samples contain high levels of HAMA, a negative bias may be observed. The interference is most critical in patients with distant metastasis where HAMA interference may impact clinical decision-making regarding additional patient management / treatment.

In cases where interference is suspected, carefully evaluate the results and laboratories should follow their validated process for identifying HAMA interference.

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4.7. High Dose Hook Effect

The high-dose hook effect was assessed on one **cobas e** 411 analyzer by using dilution series. The claim of no hook effect up to 1 µg/mL was fulfilled.

4.8. Endogenous Interferences

The effect on quantitation of Calcitonin in the presence of eight endogenous interfering substances (Biotin, Lipemia, Bilirubin, Hemoglobin, Rheumatoid Factor, Human IgG, Human IgM, Human IgA) was tested using serum samples. No interference for the assay was observed up to the concentrations of the potential interfering substances tested as shown in the table below.

Compound	Concentration tested
Bilirubin	≤ 1128 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.124 mmol/L or ≤ 200 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Rheumatoid factors	≤ 1200 IU/mL
IgG	≤ 4 g/dL
IgA	≤ 0.7 g/dL
IgM	≤ 0.4 g/dL

4.9. Analytical Specificity/Cross-Reactivity

A cross-reactivity study was conducted with Elecsys Calcitonin on the **cobas e** 411 analyzer to evaluate the potential cross-reacting compounds using. Samples were measured in the presence and absence of the potential cross-reactants and cross-reactivity was calculated with one lot of reagent. No cross reactivity was observed.

Cross-reactant	Maximum concentration tested (ng/mL)	Highest cross-reactivity observed (%)
Salmon calcitonin	200	0.000
Porcine calcitonin	1000	0.000
Chicken calcitonin	1000	0.000
ACTH (1-39) human	200	0.000

Cross-reactant	Maximum concentration tested (ng/mL)	Highest cross-reactivity observed (%)
C-peptide	80000	0.000
Calcitonin Gene Related Peptide	2000	0.000
PTH (1-84) human	300	0.000
TSH	2000 µIU/mL	0.000
Insulin	67000	0.000
Prolactin	2000	0.000
Gastrin I	4000	0.000
Elcatonin	200000	0.000
Katacalcin	80000	0.000

4.10. Exogenous Interferences – Drugs

Seventeen pharmaceutical compounds and twelve special thyroid drugs were spiked into serum samples at two concentration levels. Interference was tested according to CLSI guideline EP07-A3. The predefined acceptance criteria were met for all drugs tested and no interference was observed.

Communly used Drugs	No interference up to
Acetylcystein	150 mg/L
Ampicillin-Na	75 mg/L
Ascorbic Acid	52.5 mg/L
Cyclosporine	1.8 mg/L
Cefoxitin	750 mg/L
Heparin	3300 IU/L
Levodopa	7.5 mg/L
Methyldopa + 1.5	22.5 mg/L
Metronidazole	123 mg/L
Phenylbutazone	321 mg/L
Doxycyclin	18 mg/L
Acetylsalicylic Acid	30 mg/L
Rifampicin	48 mg/L
Acetaminophen	156 mg/L
Ibuprofen	219 mg/L

Theophylline	60 mg/L
Itraconazole	20 mg/L
Special Thyroid Drugs	**Concentration of spiked drug tested (mg/L)**
Iodide	100
Levothyroxine	1
Carbimazole	30
Thiamazole	80
Propylthiouracil	60
Perchlorate	2000
Propranolol	240
Amiodarone	200
Prednisolone	100
Hydrocortisone	200
Fluocortolone	100
Octretide	0.3

4.11. Method Comparison

A method comparison study was performed in concordance with the CLSI guideline EP09-A3 between the Elecsys Calcitonin biotin updated assay and the current Elecsys Calcitonin assay. Samples span the measuring range. A regression analysis for slope and intercept was performed for the biotin updated assay against the current assay.

The sample concentrations were between 1.07 and 1817 pg/mL for 120 samples:

Passing/Bablock	Linear regression
$y = 0.983x + 0.318$	$y = 1.01x + 0.203$
$\tau = 0.951$	$r = 0.996$

4.12. Stability

The stability studies were performed on one **cobas e** 411 analyzer. The predefined acceptance criteria were met. The stability data supports the claims as reported in labeling:

Stability:	
unopened at 2-8 °C	up to the stated expiration date
After opening at 2-8 °C	84 days (12 weeks)
on the analyzer	28 days (4 weeks)

4.13. Calibration Stability

4.13.1. Lot Calibration Stability

Lot calibration frequency for the Elecsys Calcitonin assay was tested on one **cobas e** 411 analyzer. Calibration of an Elecsys Calcitonin reagent lot is recommended every 8 weeks when using the same reagent lot.

4.13.2. On-board Calibration Stability

Reagent on-board calibration frequency for Elecsys Calcitonin assay was tested on one **cobas e** 411 analyzer. Elecsys Calcitonin reagent kits can be stored on-board of the analyzers for up to 7 days without a new calibration, when using the same reagent kit on the analyzer.

5. CLINICAL PERFORMANCE EVALUATION

Not Applicable

6. ADDITIONAL INFORMATION

Elecsys Calcitonin is intended to be used with the following calibrators and controls:

- CalSet Calcitonin
- PreciControl Varia

There have been no changes to these items marketed with the new Elecsys Calcitonin assay.

7. CONCLUSION

The analytical performance data for Elecsys Calcitonin assay met the acceptance criteria and support the substantial equivalence of Elecsys Calcitonin assay on cobas e 411 analyzer to the predicate.