September 15, 2023

Roche Diagnostics
Phil Williams
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Indiana 46250

Re: K222610
Trade/Device Name: Elecsys Anti-Tg
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO
Dated: May 19, 2023
Received: May 19, 2023

Dear Phil Williams:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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)*
K222610

Device Name
Elecsys Anti-Tg

Indications for Use *(Describe)*
Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg autoantibodies determination is used as an aid in the detection of autoimmune thyroid diseases in conjunction with other laboratory and clinical findings.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas e 411 immunoassay analyzer.

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 Anti-Tg
510(k) Summary

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Phil Williams Phone: 317-209-5478 Email: phil.williams@roche.com
Date Prepared	August 25, 2022
Proprietary Name	Elecsys Anti-Tg
Common Name	Thyroid autoantibody immunological test system
Classification Name	System, Test, Thyroid Autoantibody
Product Codes, Regulation Numbers	JZO, 21 CFR 866.5870
Predicate Devices	Roche Diagnostics Elecsys Anti-Tg (K053426)
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 Anti-Tg immunoassay makes use of a competitive test principle using biotinylated human antigen and monoclonal human anti-Tg antibodies labeled with a ruthenium complex. The Elecsys Anti-Tg immunoassay is intended for the quantitative determination of antibodies to thyroglobulin in human serum and plasma. It is intended for use on the **cobas e** immunoassay analyzers.

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 or e barcode.

1.1. Reagents

The reagent working solutions include:

Rack Pack (kit placed on the analyzer)

- M: Streptavidin-coated microparticles
- R1: Tg~biotin
- R2: Anti Tg-Ab~$Ru(bpy)_3^{2+}$

2. INDICATIONS FOR USE

Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg autoantibodies determination is used as an aid in the detection of autoimmune thyroid diseases in conjunction with other laboratory and clinical findings.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the **cobas e** 411 immunoassay analyzer.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the Elecsys Anti-Tg with its predicate device, Roche Elecsys Anti-Tg (K053426).

Feature	Candidate Device Elecsys Anti-Tg	Predicate Device Roche Elecsys Anti-Tg (K053426)
Intended Use	Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg autoantibodies determination is used as an aid in the detection of autoimmune thyroid diseases in conjunction with other laboratory and clinical findings. The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** 411 immunoassay analyzer.	Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.
Assay Method	Competitive	Same
Test type	Quantitative	Same
Detection Method	Electrochemiluminescence "ECLIA"	Same
Application Time	18 minute	Same
Assay protocol	Sample + R1, 1st incubation R2 + Beads, 2nd incubation	Same
Handling of R1 and R2	Liquid, ready to use	Same
Sample Type/Matrix	Human serum, plasma	Same
Sample Anticoagulants	K_2/K_3-EDTA	Sodium heparin, K_2/K_3-EDTA
Pipetting volume sample	10 µL	Same
Calibrator	Anti-Tg CalSet	Included in Test Kit as Anti-Tg calibrator 1 and Anti-Tg calibrator 2
Calibration Method	2-point calibration	Same

Feature	Candidate Device Elecsys Anti-Tg	Predicate Device Roche Elecsys Anti-Tg (K053426)
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 1 month (28 days) 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	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). Renewed calibration is recommended as follows: • after 1 month (28 days) 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
Controls	PreciControl ThyroAB	Included in Test Kit as PreciControl Anti-Tg 1 and PreciControl Anti-Tg 2
Traceability/Standardization	Standardized against the NIBSC (National Institute for Biological Standards and Control) 65/93 Standard	Same
Reagent Stability	• unopened at 2-8 °C: up to the stated expiration date • after opening at 2-8 °C: 6 weeks • on the analyzer: 6 weeks	Same
Measuring Range	15 – 4000 IU/mL	10 – 4000 IU/mL
Biotin Tolerance	≤ 1200 ng/mL	≤ 60 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 measurements were conducted for the updated Elecsys Anti-Tg to evaluate repeatability (within-run precision) and the intermediate precision (within-laboratory precision)

according the CLSI guideline EP05-A3. All predefined acceptance criteria was met for the precision experiments.

cobas e 411 analyzer					
		Repeatability		**Intermediate precision**	
Sample	Mean IU/mL	SD IU/mL	CV %	SD IU/mL	CV %
Human serum 1	15.7	1.32	8.4	2.28	14.5
Human serum 2	110	7.78	7.1	8.29	7.6
Human serum 3	1953	64.0	3.3	77.4	4.0
Human serum 4	2495	106	4.2	125	5.0
Human serum 5	3816	171	4.5	171	4.5
PC[b)] THYRO1	79.4	5.41	6.8	6.68	8.4
PC THYRO2	177	14.0	7.9	17.2	9.7

4.1.2. Lot-to-lot Reproducibility

Precision measurements were conducted according to CLSI guideline EP05-A3 to evaluate Lot-to-Lot Reproducibility using three reagent lots. 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 9 IU/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 10 IU/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 15 IU/mL.

4.3. Linearity

Linearity of the Elecsys Anti-Tg assay was assessed according to CLSI EP06-Ed2, study design B, using weighted linear regression analysis. Six dilution series, using native human serum samples and sample pools, were measured on the **cobas e** 411 analyzer to demonstrate that measurements across the claimed measuring range are linear. Linearity was confirmed to support the measuring range of 15 – 4000 IU/mL.

4.4. Endogenous Interferences

Six endogenous substances were evaluated for potential interference with the Elecsys Anti-Tg assay on the **cobas e** 411 analyzer. All predefined acceptance criteria were met, and the proposed labeling claims for each endogenous substance can be found below:

Biotin ≤ 1200 ng/mL

Lipemia (Intralipid) ≤ 2000 mg/dL

Hemoglobin ≤ 600 mg/dL for sample concentrations ≤ 115 IU/mL

Bilirubin ≤ 66 mg/dL

Rheumatoid Factor ≤ 300 IU/mL

Tg ≤ 100 ng/mL

4.5. Analytical Specificity/Cross-Reactivity

A cross-reactivity study was conducted with Elecsys Anti-Tg on the **cobas e** 411 analyzer to evaluate the potential cross-reactivity of the assay with anti-TPO. There was no cross-reaction with Anti-TPO detected.

4.6. Exogenous Interferences

An exogenous interference study was conducted to evaluate 17 commonly and 14 specially used pharmaceutical compounds for potential interference with the Elecsys Anti-Tg assay on the **cobas e** 411 analyzer. The predefined acceptance criteria was met for all drugs tested, and no interference was observed.

4.7. Sample Matrix Comparison

The effect on quantitation of analyte in the presence of anticoagulants with Anti-Tg was determined by comparing values obtained from native human serum samples and sample pools drawn into serum, K_2-EDTA, and K_3-EDTA plasma primary tubes. Serum separation tubes from 3 separate manufacturers and blood from 13 donors were measured in duplicate with one reagent lot and evaluated on the basis of recovery relative to the serum tube without separating gel. The results were within specification and support the use of Serum collected using standard serum tubes or tubes containing separating gel, K_2-EDTA, and K_3-EDTA plasma.

4.8. Method Comparison to Predicate

A method comparison was performed using the Elecsys Anti-Tg updated assay and the Elecsys Anti-Tg current assay, using a total of 129 human serum samples. The sample concentrations were between 23.1 and 3609 IU/mL. The results can be found below:

Linear Regression

$y = 0.905x + 48.0$

$r = 0.990$

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$y = 0.974x + 1.72$

$\tau = 0.930$

4.9. Reagent Stability

4.9.1. Reagent On-board Stability

On-board reagent stability for the Elecsys Anti-Tg assay was tested on one **cobas e** 411 analyzer. Elecsys Anti-Tg reagent kits can be stored on-board the analyzers for up to 42 days (6 weeks). A new calibration of the kit kept on-board is recommended every 7 days.

4.9.2. Reagent Stability After First Opening

Reagent stability after first opening for the Elecsys Anti-Tg assay was tested on one **cobas e** 411 analyzer. Elecsys Anti-Tg reagent kits can be used after first opening for up to 42 days (6 weeks) when stored at 2-8°C.

4.10. Calibration Stability

4.10.1. Lot Calibration Stability

Lot calibration frequency for the Elecsys Anti-Tg assay was tested on one **cobas e** 411 analyzer. Calibration of an Elecsys Anti-Tg reagent lot is recommended every 28 days (1 month). During that time period, fresh reagent kits of the same lot can be used without calibration using the calibration curve of the day 0 reagent kit.

4.10.2. On-board Calibration Stability

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

5. EXTERNAL (CLINICAL) TESTING

Not Applicable

6. CLINICAL PERFORMANCE EVALUATION

Not Applicable

7. ADDITIONAL INFORMATION

The Elecsys Anti-Tg is intended to be used with the following calibrators and controls:

- Anti-Tg CalSet
- PreciControl ThyroAB

The Anti-Tg CalSet is regulated under product code JIS and 21 CFR 862.1150 and is exempt from Premarket notification and therefore, is not included with this submission.

The PreciControl ThyroAB is regulated under product code JJY and 21 CFR 862.1660 and is exempt from Premarket notification and therefore, is not included with this submission.

8. CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports the determination that the Elecsys Anti-Tg immunoassay (updated assay, Mat. No. 09004998160) is substantially equivalent to the predicate device, Elecsys Anti-Tg system (current assay, Mat. No. 06368697190).