DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 23, 2017

ROCHE DIAGNOSTICS
ANGELO PEREIRA
REGULATORY AFFAIRS SENIOR PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250 US

Re: K162606
Trade/Device Name: Elecsys TSH assay, Cobas e 801 immunoassay Analyzer
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JWL, JJE
Dated: December 20, 2016
Received: December 21, 2016

Dear Angelo Pereira:

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 regulation (21 CFR Part 801), 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" (21CFR 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, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162606

Device Name
cobas e 801 immunoassay Analyzer
Elecsys TSH assay

Indications for Use *(Describe)*

cobas e 801 immunoassay analyzer is intended for the in-vitro determination of analytes in body fluids.

Elecsys TSH immunoassay is intended for the in vitro quantitative determination of thyrotropin in human serum and plasma. Measurements of TSH are used in the diagnosis of thyroid or pituitary disorders. The Elecsys TSH immunoassay is an electrochemiluminescence immunoassay 'ECLIA', which is intended for use on the 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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k162606

Cobas e 801analyzer –Elecsys TSH

510(k) Summary

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

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0416
Contact	Angelo Pereira Phone: (317) 521-3544 FAX: (317) 521-2324 Email: angelo.pereira@roche.com
Date Prepared	January 23, 2017
Proprietary Name	**cobas e** 801 Immunoassay analyzer; Elecsys TSH assay
Common Name	Immunoassay analyzer; Thyroid-stimulating hormone test system
Classifications	21CFR862.2160, Chemistry analyzer; Class I 21CFR862.1690, Thyroid-stimulating hormone test system Class II
Product Codes	JJE JLW
Predicate Devices	**Elecsys** 2010/ Elecsys TSH K961491
Establishment Registration	For **cobas e** 801 and Elecsys TSH, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126, and for Penzberg, Germany, 9610529. The establishment registration number for Roche Diagnostics in the United States is 1823260.

1. DEVICE DESCRIPTION

The **cobas e** 801 immunoassay analyzer is a fully automated, software controlled analyzer system for in vitro determination of analytes in human body fluids. It is part of the **cobas** 8000 modular analyzer series cleared under K100853. It uses electrochemiluminescent technology for signal generation and measurement.

2. INTENDED USE

cobas e 801 immunoassay analyzer is intended for the in vitro determination of analytes in body fluids.

Elecsys TSH is an immunoassay for the in vitro quantitative determination of thyroid stimulating hormone in human serum and plasma. Measurement of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid and pituitary disorders. The electrochemiluminescence immunoassay 'ECLIA' is intended for use on the cobas e immunoassay analyzers.

3. DEVICE TO WHICH EQUIVALENCE IS CLAIMED

The **cobas e** 801 analyzer module is a modified version of the predicate device, the Elecsys 2010 with Elecsys TSH as the representative quantitative assay, cleared under K961491.

A comparison of the significant features of the **cobas e** 801 and the Elecsys 2010 is provided in the table below.

Table 1: Similarities and differences between the cobas e 801 and Elecsys 2010 analyzers

Topic	Predicate device: Elecsys 2010 analyzer	Candidate device:cobas e801 analyzer module
Basic Features		
Intended Use	Intended for the in vitro determination of analytes in body fluids.	Same
Measurement principle	Electrochemiluminescence immunoassay method (ECLIA)	Same
Workflow principle	Batch or random access	Same
Throughput	86 tests/hour	300 tests/hour/module

Topic	Predicate device: Elecsys 2010 analyzer	Candidate device:cobas e801 analyzer module
Sample Handling		
Typical sample volumes	10-50µL	4-60 µL
Sample types	Serum, plasma, urine, saliva	Same
Sample handling system	Via sample disk or racks	Input and transport of samples using universal sample racks, modular sample buffer input, core/transportation unit and STAT port.
Sample capacity on board	Disc: 30; rack:75	300
Sample identification	Positive id-yes	Same
Reagent Handling		
Reagent volume	10-190 µL	6-60 µL
Onboard storage temperature	18-22°C	5-10°C
Reagent bottle/Cassette identification	2-d barcode	RFID
Application information transfer to instrument	Via barcode on reagent pack	Electronic transfer via cobas link
Test Reaction Chamber		
Temp. control	Incubation at 37°C.	Same
Detection		
Measuring unit	1	2
Detection unit	ECL unit with sipper, measuring cell and photomultiplier	Design of the sipper changed to shorten the detection cycle time; measuring cell and photomultiplier are the same
Detection time	1.2 seconds	Same
Detection cycle time	42 sec	24 sec
Software		
Software	Elecsys 2010 Software	cobas 8000 modular System Software
Configuration	Stand alone	One PC and one core in combination with several e-modules or c analytical modules
Analytical Unit(s) functions	Control of analytic processes (pipetting, incubation, detection) and Primary Signal processing	Same
Result calculation	Automated measuring of ECL signal and automated calculation of concentrations via calibration curve	Same

Elecsys TSH was used as the representative assay for this submission. Comparative data for the Elecsys TSH assay run on the **cobas e** 801 and the Elecsys 2010 is provided in the table below.

Table 2: Similarities and Differences for Elecsys TSH on cobas e 801 versus Elecsys 2010

Feature	Predicate Device: Elecsys TSH on Elecsys 2010 analyzer (K 9 6 1 4 9 1)	Candidate Device: Elecsys TSH on cobas e801 analyzer module
Intended Use	Immunoassay for the in vitro quantitative determination of thyroid stimulating hormone in human serum and plasma	Same
Instrument Platform	Elecsys immunoassay analyzer	Elecsys immunoassay analyzer, part of the cobas 8000 modular analyzer series (K100853)
Measurement principle	Electrochemiluminescence immunoassay (ECLIA) method	Same
Antibody/ Reagents	Biotinylated monoclonal anti-TSH antibody (mouse) Monoclonal anti-TSH antibody (mouse/human) labeled with ruthenium complex Streptavidin –coated microparticles	Same
Sample size	50 µL of sample	30µL of sample
Measuring Range	0.005-100 µIU/mL	Same
Sample Types	Serum, serum with separating gel, Li-heparin, K_2EDTA, K_3EDTA Also, Sodium citrate and NaF/K oxalate	Serum, serum with separating gel, Li-heparin, K_2EDTA and K_3EDTA.

4. PERFORMANCE CHARACTERISTICS

4.1. Repeatability and Intermediate Precision

Precision of the Elecsys TSH assay was evaluated on one **cobas e** 801 analyzer according to CLSI EP05-A3. One reagent lot was evaluated.

The protocol consisted of testing 2 replicates of each control (PC Universal and PreciControl TS) and human sera (HS) per run, 2 runs per day for 21 days. The samples were run in randomized order on the analyzer. Pooled serum samples were used (Human serum 1-5, 11) and pooled spiked sera (Human serum 6-10).

The results of the precision studies are given in the table below:

		Repeatability		Intermediate precision	
Sample	Mean (µIU/mL)	SD (µIU/mL) (SD 95% UCL)	CV (%) (UCL* 95%)	SD (µIU/mL) (SD 95% UCL)	CV (%) (UCL* 95%)
Human serum 1	0.00851	0.000600 (0.000734)	7.1 (8.6)	0.000962 (0.00118)	11.3 (13.8)
Human serum 2	0.209	0.00338 (0.00412)	1.6 (2.0)	0.00520 (0.00624)	2.5 (3.0)
Human serum 3	1.88	0.0264 (0.0322)	1.4 (1.7)	0.0432 (0.0533)	2.3 (2.8)
Human serum 4	51.8	0.653 (0.797)	1.3 (1.5)	1.05 (1.26)	2.0 (2.4)
Human serum 5	90.0	1.24 (1.52)	1.4 (1.7)	1.75 (2.07)	1.9 (2.3)
PC Universal 1	1.41	0.0197 (0.0240)	1.4 (1.7)	0.0301 (0.0362)	2.1 (2.6)
PC Universal 2	8.18	0.132 (0.161)	1.6 (2.0)	0.207 (0.250)	2.5 (3.1)
PreciControl TS	0.184	0.00325 (0.00397)	1.8 (2.2)	0.00417 (0.00495)	2.3 (2.7)

4.2. Linearity

Linearity of the Elecsys TSH assay was assessed on the **cobas e** 801 Immunoassay Analyzer according to CLSI EP6-A. Three high analyte serum samples were diluted with Diluent MultiAssay. 12 concentrations (dilutions) throughout the measuring range were prepared. Samples were assayed in 3-fold determination within a single run. The linearity data were analyzed with regards to linear, quadratic and cubic polynomials according to CLSI EP6-A. A summary of the linearity data is presented below:

Serum 1: intercept = -0.00155, slope = 0.963, Pearson’s r = 0.9994

Serum 2 intercept = -0.00193, slope = 0.958, Pearson’s r = 0.9992

Serum 3 intercept = -0.00272, slope = 0.952, Pearson’s r = 0.9986

4.3. Analytical sensitivity

The limit of Blank (LoB) determines the highest observed measurement values for samples free of analyte. It was determined for three reagent lots using 60 replicates (one **cobas e** 801 instrument, six days, one run per day, one blank sample with ten replicates per run). LoB is 0.0025 µIU/mL

The Limit of Detection (LoD) was determined as the lowest amount of analyte in a sample that can be detected with 95% probability. It was determined for three reagent lots using 60 replicates (one **cobas e** 801 instrument, six days, one run per day, two replicates per sample per run and five low-level human serum samples). LoD is 0.005 µIU/mL.

The Limit of Quantitation (LoQ) is defined as the mean value of that sample which is the first that fulfills the specification for the intermediate precision and for which no sample with higher concentration exists that exceeds this specification. It was determined for three reagent lots using 10 low level TSH samples tested on one instrument, for five days, one run per day and five replicates per sample. The mean value and the intermediate precision as coefficient of variation (CV) and standard deviation (SD) for each LoQ sample were then calculated. The LoQ is 0.005 µIU/mL at a CV≤ 20 %.

4.4. Endogenous interferences

The effect on quantitation of analyte in the presence of endogenous interfering substances using the Elecsys TSH was determined on the **cobas e** 801 Immunoassay analyzer using human serum samples. No interference was observed up to the levels indicated:

Interferent	No interference seen up to	
Intralipid (Lipemia)	**2000**	**mg/dL**
Biotin	**56.0**	**ng/mL**
Bilirubin	**66.0**	**mg/dL**
Hemoglobin	**1000**	**mg/dL**
Rheumatic Factor	**1500**	**IU/mL**
human IgG	**2.80**	**g/dL**
human IgM	**0.500**	**g/dL**

4.5. Exogenous interferences- anticoagulants

The effect on quantitation of analyte in the presence of anticoagulants with the Elecsys TSH Immunoassay was determined by comparing values obtained from samples (single donors, native as well as spiked) drawn into Serum, Li-Heparin, K2-EDTA and K3-EDTA plasma tubes. Anticoagulants: A minimum of 40 serum/plasma pairs per sample material were tested in singleton with one reagent lot on one **cobas e** 801 Immunoassay Analyzer. Data were evaluated using a regression analysis according to Passing/Bablok and supported the above sample types.

4.6. Exogenous interferences- drugs

In vitro tests were performed on 16 commonly used drugs. No interference with the assay was found. In addition the following special drugs were tested. No interference with the assay was found to the levels tested:

Drug	**Concentration tested (mg/L)**
Amiodarone	200
Carbimazole	30
Fluocortolone	100
Hydrocortisone	200
Iodide	0.2
Levotyroxine	0.25
Liothyronine	0.015
Methimazole	80
Octreotide	0.3
Prednisolone	100
Propanolol	240
Propylthiouracil	60
Perchlorate	2000

4.7. Method comparison

A method comparison was performed between the cobas e 801 and the predicate Elecsys 2010. A total of 130 human serum samples (single donors and serum pools; native, spiked as well as diluted) were measured with the Elecsys TSH immunoassay on analyzers in singlicate covering

the entire measuring range. Sample concentrations were between 0.008 – 92.6 µIU/mL. The summary of the analysis is presented in the table below:

	Passing/Bablok	**Linear regression**
N	130	
Slope	0.936	0.958
Intercept	-0.003	-0.052
Correlation coefficient Pearson (r) Kendall (τ)	- 0.989	0.999 -

4.8. Expected Values

0.27-4.20 µIU/mL

These values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 516 healthy test subjects examined.

CONCLUSION

The Elecsys TSH assay applied to the **cobas e** 801 analyzer is substantially equivalent to the predicate device based on the intended use, principle and performance characteristics described above.