June 22, 2018

Roche Diagnostics
Adennis Cora
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Indiana 46250

Re: K181492
Trade/Device Name: Elecsys CA 15-3 II
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: MOI
Dated: June 5, 2018
Received: June 6, 2018

Dear Adennis Cora:

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 Part 801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kelly Oliner -S

For
Lea Carrington
Director
Division of Immunology
and Hematology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181492

Device Name
Elecsys CA 15-3 II

Indications for Use *(Describe)*

Immunological in vitro assay for quantitative determination of CA 15-3 in human serum, Li-heparin and EDTA plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid

- in the early detection of recurrence in previously treated stage II and III breast cancer patients
- for monitoring response to therapy in metastatic breast cancer patients

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.

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

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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

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

The assigned 510(k) number is K181492

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Adennis Cora Phone: (317) 521-3915 FAX: (317) 521-2324 Email: adennis.cora_gress@roche.com
Date Prepared	May 10, 2018
Proprietary Name	Elecsys CA 15-3 II
Common Name	Elecsys Cancer Antigen 15-3 II
Classification Name	System, Test, Immunological, Antigen, Tumor
Product Codes, Regulation Numbers	MOI, 866.6010
Predicate Devices	Elecsys CA 15-3 II (K171605)
Establishment Registration	For the Elecsys CA 15-3 II, the establishment registration number for Roche Diagnostics GmbH manufacturing in Penzberg, Germany is 9610529, and for Roche Diagnostics GmbH packaging in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics in the United States is 1823260.

1. DEVICE DESCRIPTION

The Elecsys CA 15-3 II Test System is a two-step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection for the quantitative determination of CA 15-3 in human serum, Li-heparin plasma and EDTA plasma. It is intended for use on the **cobas e** 801 immunoassay analyzer. The **cobas e** family of analyzers employs the electrochemiluminescence "ECLIA" technology.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided via the cobas link.

1.1. Reagents

The **cobas e** pack includes:

- Streptavidin-coated microparticles
- Reagent 1 (Biotinylated monoclonal antibody (115D8; mouse) 1.75 mg/L)
- Reagent 2 (Monoclonal anti-CA 15-3 antibody (DF3; mouse) labeled with ruthenium complex 10 mg/L)

1.2. Calibration

Traceability: This method has been standardized against the Elecsys CA 15-3 assay. This in turn has been standardized against the Enzymun Test CA 15 3 method and CA 15-3 RIA by Fujirebio Diagnostics. The predefined master curve is adapted to the analyzer using the relevant CalSet.
Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analyzer). Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

1.3. Control

PreciControl Tumor Marker is used for the quality control verification of the performance of the assay on the **cobas e** analyzers.

2. INDICATIONS FOR USE

Immunological in vitro assay for quantitative determination of CA 15□3 in human serum, Li-heparin and EDTA plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid

- in the early detection of recurrence in previously treated stage II and III breast cancer patients
- for monitoring response to therapy in metastatic breast cancer patients

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

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the Elecsys CA 15-3 II with its predicate device, CA 15-3 (K171605). In summary, the Elecsys CA15-3 II described in this submission is substantially equivalent to the predicate device.

Feature	Predicate	Candidate
Assay	**CA 15-3 II (Cleared K171605)**	**Elecsys CA 15-3 II (K181492)**
Intended use	Immunological in vitro assay for quantitative determination of CA 15-3 in human serum and Li-heparin plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid • in the early detection of recurrence in previously treated stage II and III breast cancer patients • for monitoring response to therapy in metastatic breast cancer patients The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.	Immunological in vitro assay for quantitative determination of CA 15-3 in human serum, Li-heparin and EDTA plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid • in the early detection of recurrence in previously treated stage II and III breast cancer patients • for monitoring response to therapy in metastatic breast cancer patients The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Feature	Predicate	Candidate
Sample Type	Human serum and Li-heparin plasma	Human serum, Li-heparin and K_2-EDTA plasma
Analytical Specificity	Based on monoclonal 115D8 and DF3 antibodies available from Fujirebio Diagnostics, its licensees and its representatives	Same
Instrument Platform	**cobas e** 801	Same
Measuring Range	3 – 300 U/mL Determined by LOQ (Per EP17-A2)	Same
Calibrator	CA 15-3 II CalSet	Same
Control	PreciControl Tumor Marker	Same
Traceability	The method has been standardized against the Enzymun-Test CA 15-3 method. This in turn has been standardized against the CA 15-3 RIA from Fujirebio Diagnostics.	Same
Prewash	Prewash needed	Same

4. NON-CLINICAL PERFORMANCE EVALUATION

Non-clinical performance evaluation for the Elecsys CA 15-3 II are briefly summarized below:

4.1. Precision

Precision and reproducibility of the Elecsys CA 15-3 II were demonstrated under K171605.

4.2. Analytical Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) of the Elecsys CA 15-3 II were demonstrated under K171605.

4.3. High-Dose Hook Effect

High-Dose Hook Effect of the Elecsys CA 15-3 II was demonstrated under K171605.

4.4. Linearity/Assay Reportable Range

Linearity/Assay Reportable Range of the Elecsys CA 15-3 II was demonstrated under K171605.

4.5. Endogenous Interferences

Endogenous Interferences of the Elecsys CA 15-3 II was demonstrated under K171605.

4.6. Exogenous Interferences – Anticoagulants

4.6.1 Serum/Li-Heparin Plasma Comparison

The performance of the Elecsys CA 15-3 II using Li-heparin plasmas sample comparing to serum sample on the **cobas** e 801 analyzer was demonstrated under K171605.

4.6.2 Serum/K_2-EDTA Plasma Comparison

A study was performed to demonstrate that K_2-EDTA plasma samples yield comparable values as serum samples by the Elecsys CA 15-3 II assay on the **cobas e** 801 analyzer. 44 serum/plasma paired samples were tested in singleton with one reagent lot on one **cobas e** 801 Immunoassay Analyzer. Potential effects were assessed by Passing/Bablok regression analysis. The data are summarized in the following table:

	N	Range (U/mL)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Serum vs. K_2-EDTA Plasma	44	8.37–298	0.985 (0.955–1.036)	-0.279 (-1.143 – 0.288)	0.997

Conclusion:

The 44 serum/plasma pairs fulfilled the acceptance criteria for Passing Bablock Analysis. The data supports the addition of K_2-EDTA plasma type.

4.7. Method Comparison to cobas e 601 Immunoassay Analyzer

Method Comparison of the Elecsys CA 15-3 II on the **cobas e** 801 to the **cobas e** 601 immunoassay analyzer was demonstrated under K171605.

4.8. Stability (Reagent, Sample, Calibration)

Stability (Reagent, Sample, Calibration) of the Elecsys CA 15-3 II was demonstrated under K171605.

5. CONCLUSIONS

The information provided in this 510(k) Premarket Notification will support extending the sample type to include K_2-EDTA plasma for the Elecsys CA 15-3 II test system on **cobas e** 801. The data supports a safe, effective device which performs as well as the predicate device.