October 12, 2022

Roche Diagnostics
Bin Sun
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, Indiana 46250

Re: K220911
Trade/Device Name: Elecsys CMV IgG
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus Serological Reagents
Regulatory Class: Class II
Product Code: LFZ
Dated: March 28, 2022
Received: March 29, 2022

Dear Bin Sun:

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

801and 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,

Maria Garcia, Ph.D.
Assistant Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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.

Submission Number *(if known)*

Device Name

Elecsys CMV IgG (09118551190)

Indications for Use *(Describe)*

The Elecsys CMV IgG assay is an in vitro qualitative test for the detection of IgG antibodies to CMV in human serum, lithium-heparin plasma, K2-EDTA plasma, and K3-EDTA plasma. The test is intended as an aid in the determination of the serological status to CMV in individuals in which a CMV IgG test was ordered, including pregnant women.
Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at point of care facilities. This test is not intended for use in screening blood and plasma donors.
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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510(k) Summary

Prepared on: 2022-03-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Roche Diagnostics
Applicant Address	9115 Hague Road Indianapolis IN 46250 United States
Applicant Contact Telephone	317-292-3781
Applicant Contact	Mr. Bin Sun
Applicant Contact Email	bin.sun.bs2@roche.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Elecsys CMV IgG (09118551190)
Common Name	Cytomegalovirus serological reagents
Classification Name	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus
Regulation Number	866.3175
Product Code	LFZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K131605	Elecsys CMV IgG Immunoassay	LFZ

Device Description Summary

21 CFR 807.92(a)(4)

Elecsys CMV IgG is a two-step sandwich immunoassay with streptavidin microparticles, biotinylated recombinant CMV-specific antigen labeled with a ruthenium complex and electrochemiluminescence detection. The results are determined using a calibration curve which is instrument-specifically generated by a 2-point calibration and a master curve provided via the reagent bar code. Results greater than or equal to 1.0 U/mL are considered reactive CMV IgG antibody. The test system contains the human serum-based calibrators intended for use with the system.
Elecsys PreciControl CMV IgG contains liquid control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys CMV IgG immunoassay.
Note: The reagent and calibrators are packaged together in the Elecsys CMV IgG assay kit, while the associated PreciControl is packaged separately.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Elecsys CMV IgG assay is an in vitro qualitative test for the detection of IgG antibodies to CMV in human serum, lithium-heparin plasma, K2-EDTA plasma, and K3-EDTA plasma. The test is intended as an aid in the determination of the serological status to CMV in individuals in which a CMV IgG test was ordered, including pregnant women.
Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at point of care facilities. This test is not intended for use in screening blood and plasma donors.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Elecsys CMV IgG (updated assay, Mat. No. 09118551190) is substantially equivalent to Elecsys CMV IgG, cleared under K131605.

The intended use of Elecsys CMV IgG was updated to remove analyzers that are no longer supported for use with Roche assays. The indications for use of updated Elecsys CMV IgG assay did not change from the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Roche Diagnostics has updated the current Elecsys CMV IgG assay in order to improve the biotin tolerance from ≤ 100 ng/mL to ≤ 1200 ng/mL and to reduce streptavidin interference. A technical solution was implemented by adding an anti-biotin antibody to one of the reagents, which allows depletion of biotin in patient samples by binding free biotin, and by adding a streptavidin interference reducing agent to enhance the streptavidin tolerance. No other technological characteristics were changed. The information submitted in this Premarket Notification supports a substantial equivalent decision.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1. Precision
The precision of the Elecsys CMV IgG assay was evaluated on one cobas e 801 immunoassay analyzer with one reagent lot. The protocol consisted of testing 2 aliquots of each of three levels of controls and 5 human serum samples per run, 2 runs per day for 21 days. The samples were run in randomized order on the analyzer. Repeatability and Intermediate imprecision were calculated according to CLSI EP05-A3 including the 95% confidence interval.

2. Biotin Interference
The effect on quantitation of analyte in the presence of biotin using the updated Elecsys CMV IgG assay was determined using three serum samples (negative, positive close to cut-off, positive) according to CLSI EP07-A3 Appendix A.
Native human serum pools were used for the low and mid concentration samples. The high human serum sample comprises a single serum donor. Samples were divided, and one part of each sample was spiked with the interfering endogenous substance and used as the "interference pool." Another part of the sample was spiked with the same volume of solvent as the interfering endogenous substance (without interfering substance) and used as the related "dilution pool."
A series of 11 dilution steps were prepared by mixing the interference pools and the related dilution pools.
The mean recovery (absolute deviation or percent recovery) was calculated for each sample compared to the expected value.
The maximum value with no interference observed was 2400 ng/mL. The biotin claim in the method sheet will be set to 1200 ng/mL.

3. Method Comparison to Predicate
A method comparison study was performed to demonstrate equivalency between the performance of the current Elecsys CMV IgG assay and the biotin-updated Elecsys CMV IgG assay on one cobas e 801 analyzer.
A total of 280 samples were measured with one reagent lot of the current Elecsys CMV IgG assay and three different reagent lots of the biotin-updated Elecsys CMV IgG assay in single determination on the cobas e 801 analyzer. Results are presented in a 3x3 table. Positive Agreement and Negative Agreement between the current and updated assay were calculated. The resulting data support the equivalence of the current non-biotin and biotin-updated assay.

4. Stability
The stability studies and acceptance criteria have been reviewed and found to be acceptable. The stability data supports Roche Diagnostic's claims as reported in the package labeling.

All performance specifications were met. The information provided in this 510(k) Premarket Notification is complete and supports a substantial equivalence decision. The data from the analytical studies demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device with improved biotin tolerance level up to 1200 ng/mL.

Not Applicable