DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
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Silver Spring, MD 20993-0002

March 17, 2017

Roche Diagnostics
Angelo Pereira
Regulatory Affairs Senior Program Manager
9115 Hague Road
Indianapolis, IN 46250

Re: K163569
Trade/Device Name: Elecsys CMV IgM
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents
Regulatory Class: Class II
Product Code: LFZ, JJE
Dated: December 16, 2016
Received: December 19, 2016

Dear Mr. 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 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), 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" (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 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,

Steven R. Gitterman -S

for Uwe Scherf, Ph.D.
Director
Division of Microbiology 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)*
K163569

Device Name
Elecsys CMV IgM

Indications for Use *(Describe)*
Immunoassay for the in vitro qualitative detection of IgM 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 diagnosis of recent or current CMV infection in individuals for which a CMV IgM 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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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."

- Elecsys CMV IgM on the cobas e 801 analyzer

510(k) Summary

This summary of 510(k) substantial equivalence 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	March 09, 2017
Proprietary Name	Elecsys CMV IgM **cobas e** 801 Immunoassay analyzer
Common Name	CMV IgM assay Immunoassay analyzer
Classifications	21CFR866.3175, Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus Class II 21CFR862.2160, Chemistry analyzer; Class I
Product Codes	LFZ JJE
Predicate Devices	Elecsys CMV IgM on the cobas e 601 (K142133)
Establishment Registration	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

Elecsys CMV IgM is a qualitative assay for the detection of IgM antibodies to CMV in human serum and plasma for use on the **cobas** e 801 immunoassay analyzer. 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

Elecsys CMV IgM immunoassay is intended for the in vitro qualitative detection of IgM 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 diagnosis of recent or current CMV infection in individuals for which a CMV IgM 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 the **cobas** e immunoassay analyzers

3. DEVICE TO WHICH EQUIVALENCE IS CLAIMED

Elecsys CMV IgM on the **cobas** e 601 is used as the predicate assay for the Elecsys CMV IgM on the **cobas** e 801 (new device).The **cobas** e 801 analyzer module is a modified version of the predicate device, the **cobas** e 601 analyzer module, part of the **cobas** 6000 modular analyzer cleared under K060373.

Comparative properties for the Elecsys CMV IgM assay run on the **cobas** e 801 and the **cobas** e 601 is provided in the table below.

Table 1: Similarities and Differences for the Elecsys CMV IgM assay on cobas e 801 versus cobas e 601

Feature	Predicate Device: Elecsys CMV IgM on cobas e601 analyzer module (K142133)	Candidate Device: Elecsys CMV IgM on cobas e801 analyzer module
Intended Use	Elecsys CMV IgM immunoassay is intended for the in vitro qualitative detection of IgM 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 diagnosis of recent or current CMV infection in individuals for which a CMV IgM test was ordered, including pregnant women.	Same
Instrument Platform	Elecsys immunoassay analyzer, part of the **cobas** 6000 modular analyzer series (K060373)	Elecsys immunoassay analyzer, part of the **cobas** 8000 modular analyzer series (K100853)
Assay Protocol	µ- Capture	Same
Measurement principle	Electrochemiluminescence immunoassay (ECLIA) method	Same
Antibody/ Reagents	Biotinylated monoclonal anti-h-IgM antibody (mouse) CMV-specific antigen (recombinant, E. coli) labeled with ruthenium complex Streptavidin –coated microparticles	Same
Sample size	10 µL of sample	6 µL of sample
Sample Types	Serum, serum with separating gel, Li-heparin, K_2EDTA and K_3EDTA	Serum, serum with separating gel, Li-heparin, K_2EDTA, K_3EDTA.
Basic Features of the Instruments		
Measurement principle	Electrochemiluminescence immunoassay method (ECLIA)	Same
Workflow principle	Batch or random access	Same
Throughput	170 tests/hour/module	300 tests/hour/module
Sample Handling		
Typical sample volumes	10-50µL	4-60 µL
Sample types	Serum, plasma, urine, CSF	Same
Sample handling system	Input and transport of samples using universal sample racks, core/transportation unit and STAT port	Input and transport of samples using universal sample racks, modular sample buffer input, core/transportation unit and STAT port.
Sample capacity on board	150	300
Sample identification	Barcode	Same
Reagent Handling		

Feature	Predicate Device: Elecsys CMV IgM on cobas e601 analyzer module (K142133)	Candidate Device: Elecsys CMV IgM on cobas e801 analyzer module
Reagent volume	10-190 µL	6-60 µL
Onboard storage temperature	18-22°C	5-10°C
Reagent bottle/Cassette identification	Barcode	RFID
Application information transfer to instrument	Via barcode on reagent pack and electronic transfer via **cobas** link	Electronic transfer via **cobas** link
Test Reaction Chamber		
Temp. control	Incubation at 37°C.	Same
Detection		
Measuring unit	2	Same
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	**cobas** 6000 modular System Software	**cobas** 8000 modular System Software
Configuration	One PC and one core in combination with several e-modules or c analytical modules	Same
Functions performed	Data input, sample processing, result calculation, result reporting, quality control	Same
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

4. PERFORMANCE CHARACTERISTICS

4.1. Repeatability and Intermediate Precision

The following precision results were obtained with the Elecsys CMV IgM assay on the cobas e 801 with serum samples. Within run precision (repeatability) and intermediate precision were

determined according to CLSI Guideline EP05-A3. All results met predefined acceptance criteria.

Table 1: Summary of Precision Results for Elecsys CMV IgM

		Repeatability		Intermediate precision		
Sample	Mean [COI]	SD [COI]	CV [%]	SD [COI]	CV [%]	n
HSP 1	0.202	0.002	1.2	0.006	2.8	84
HSP 2	0.847	0.011	1.3	0.015	1.8	84
HSP 3	1.09	0.018	1.6	0.020	1.8	84
HSP 4	3.46	0.033	1.0	0.049	1.4	84
HSP 5	1.28	0.013	1.0	0.023	1.8	84
PC CMV IgM 1	0.225	0.002	0.9	0.006	2.6	84
PC CMV IgM 2	1.85	0.036	1.9	0.041	2.2	84

4.2. Analytical Sensitivity: Limit of Blank (LoB) and Limit of Detection (LoD)

The Limit of Blank (LoB) and Limit of Detection (LoD) of the Elecsys CMV IgM assay were determined according to CLSI EP17-A2 on the cobas e 801.

Table 2: LoB and LoD for Elecsys CMV IgM

LoB (COI)	LoD (COI)
0.243	0.276

Given that the Elecsys CMV IgM assay is qualitative and its LoD of 0.276 COI is well below the cut-off value of 0.7 COI, determination of a Limit of Quantiation (LoQ) is unnecessary. As such determination of the LoQ was not performed.

4.3. High Dose Hook Effect

Testing with the Elecsys CMV IgM assay was assessed on the **cobas** e 801 analyzer using serum samples with high CMV IgM concentrations using a dilution series. All results met the pre-defined acceptance criteria demonstrating no high dose hook effect for the Elecsys CMV IgM assay.

4.4. Endogenous and Drug Interferences

The effect on recovery of analyte with the Elecsys CMV IgM assay on the cobas e 801in the presence of potentially interfering endogenous substances hemoglobin, lipemia, bilirubin, biotin and rheumatoid factor was evaluated. All results met the pre-defined acceptance criteria demonstrating no interference from:

- Hemoglobin up to500 mg/dL
- Intralipid up to 1500 mg/dL
- Bilirubin up to 20 mg/dL
- Biotin up to 100 ng/mL
- Rheumatoid factor up to 899 IU/mL

4.5. Exogenous Interferences – Anticoagulants

The effect on recovery of analyte with the Elecsys CMV IgM assay in the presence of anticoagulants was determined on the **cobas** e 801 by comparing values obtained with samples drawn into serum, lithium-heparin plasma, K_2-EDTA plasma and K_3-EDTA plasma. Serum collected in tubes containing separating gel was also evaluated using the Elecsys 2010 and the E170 analyzers. All results met the pre-defined acceptance criteria, demonstrating that serum, lithium-heparin plasma, K_2-EDTA plasma and K_3-EDTA plasma and serum collected in tubes containing separating gel are acceptable sample types for use with the Elecsys CMV IgM assay.

4.6. Exogenous Interferences - Drugs

In addition, 18 commonly used drugs and two special drugs Ganciclovir and Valganciclovir were evaluated for interference with the Elecsys CMV IgM assay using the Elecsys 2010 and the **cobas** e 411. All results met the pre-defined acceptance criteria, demonstrating no interference from the drug substances tested.

4.7. Method Comparison Between Analyzer Platforms

The equivalence of the Elecsys CMV IgM assay on the **cobas** e 801 and the **cobas** e 601 was evaluated by a method comparison study. Plasma samples were measured on both analyzers.

Positive and negative agreement of the results between the two platforms were calculated and demonstrated equivalence between the analyzer platforms for the determination of IgM antibodies to CMV using the Elecsys CMV IgM assay.

Concordance Rates:

Negative Percent Agreement (NPA) = 100% (142/142)

Positive Percent Agreement (PPA) = 100% (73/73)

Agreement rate for Indeterminate was 75% (6/8)

4.8. Assay Cut-Off

The cutoff was established with in-house studies by characterizing samples using several commercially available CMV IgG and CMV IgM assays. Validation of the assay cutoff was performed by external clinical studies on the Elecsys 2010 . Since the Elecsys 2010 and the **cobas** e 801 are members of the same Elecsys family of instruments, the same cutoff has been applied to the **cobas** e 801 analyzer. Classification of samples based on the establishment, verification and validation is as follows:

Sample results < 0.7 COI = Non-reactive sample

Sample results ≥ 0.7 to < 1.0 COI = Indeterminate (Border) sample

Sample results ≥ 1.0 COI = Reactive sample

4.9. Clinical Performance

Clinical performance of the Elecsys CMV IgM assay was assessed using the Elecsys 2010. This information was included in K142133. It included a multi-center clinical study, analytical specificity, verification of IgM specificity and expected values. Since the Elecsys 2010 and the **cobas** e 801 are members of the same Elecsys family of instruments, these clinical claims are being transferred over to the **cobas** e 801 analyzer.

5. CONCLUSION

The information provided in this Premarket Notification (510(k) will support a determination of substantial equivalence for the Elecsys CMV IgM assay on the **cobas** e 801 analyzer.