March 22, 2021

Immucor, Inc.
Steven Appel
Senior Principal Regulatory Affairs Specialist
3130 Gateway Drive
Norcross, Georgia 30071

Re: K203612
Trade/Device Name: Capture-CMV
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents
Regulatory Class: Class II
Product Code: LJO
Dated: September 16, 2020
Received: December 10, 2020

Dear Steven Appel:

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,

Maria Garcia, Ph.D.
Branch Chief
Division of Microbiological Devices
Office of Health Technologies 7
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)*
k203612

Device Name
Capture-CMV®

Indications for Use *(Describe)*
Capture-CMV® is an *in vitro* qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV® is intended to be used in screening of patients for serological evidence of previous infection by CMV using manual and semi-automated methods, NEO Iris® and Galileo NEO®.

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

Date Prepared

March 16, 2021

510(k) Owner

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071
Establishment Registration Number: 1034569

Contact Information

Name of Contact:	Steven Appel
Phone Number:	770-440-2051
Fax Number:	770-242-8930

Device Name

Trade/Device Name:	Capture-CMV®
Common Name:	CMV Antibody Screen
Classification Name:	Cytomegalovirus serological reagents
Unique Device Identifier (UDI):	10888234002154

Device Class

Regulatory Class:	II
Product Code:	LJO
Regulation Number:	21 C.F.R. §866.3175
Regulation Medical Specialty:	Microbiology
Review Panel:	Microbiology

Predicate Device Information

Trade/Device Name:	Capture-CMV®
Clearance:	K183571 (cleared February 4, 2019)

Purpose of the Submission

To demonstrate performance of the Capture-CMV® assay on the upgraded Galileo NEO® (Software version 3.0.1) instrument. This is an upgrade of the Galileo NEO® (BK100033) to match the NEO Iris® instrument that was cleared via BK183571. With these changes the Galileo NEO® and NEO Iris® instruments are functionally identical; the only differences are model name, the exterior colors of the instruments, and whether the software indicates the device name as NEO Iris® or Galileo NEO®. Thus, no new studies were performed to evaluate the performance of Capture-CMV®. Instead, previous data supporting the original clearance of the Capture-CMV® assay on the NEO Iris® is presented.

Device Description

Capture-CMV® is a Solid Phase Red Cell Adherence System for the detection of IgG and IgM antibodies to Cytomegalovirus (CMV).

Cytomegalovirus (CMV) is a common human viral pathogen which belongs to the family of herpes viruses. The presence of CMV antibodies in an individual indicates prior infection by the virus. The possibility exists that viral reactivation can occur in such individuals. CMV infection is usually asymptomatic and can persist as a latent or chronic infection.

Viral transmission may occur through transfusion of blood or transplantation of organs from seropositive donors.

Immunocompromised patients, such as premature neonates, organ transplant patients, and oncology patients, are at greater risk of developing more severe manifestations of CMV infections which can be a major direct or indirect cause of mortality in such patients.

Congenitally infected newborns are especially prone to developing severe cytomegalic inclusion disease (CID). The severe form of CID may be fatal or may cause permanent neurological sequelae, such as mental retardation, deafness, microcephaly, and motor dysfunction. A CMV mononucleosis-type syndrome can result from the transfusion of CMV-infected blood products or the transplantation of CMV-infected donor organs in a seronegative immunocompromised patient. Low birth weight neonates are also at high risk to CMV mononucleosis through transfusion of CMV-infected blood products.

One method of preventing or reducing CMV infection in seronegative immunocompromised patients is to select CMV seronegative blood donors or organ donors that have been tested by serological screening test for antibodies to CMV. Capture-CMV is a solid phase red cell adherence antibody detection system based on procedures of Plapp et al. This procedure is a modification of the mixed agglutination tests for antigen and antibody detection of Coombs et al. and Hogman employing anti-IgG and IgG-coated red cells as the indicator system. Capture assays for the detection of antibodies to red cells or platelets use anti-IgG-coated red cells as the indicator. Capture-CMV uses anti-IgG plus anti-IgM-coated indicator red cells.

The CMV assay is to be used with NEO Iris® and the Galileo NEO® instruments. The NEO Iris®/Galileo NEO® is a microprocessor-controlled instrument that fully automates test processing, result interpretation and data management functions for the associated assays. The instrument is designed to automate, in addition to the CMV assay, standard immunohematology assays using a microplate-based platform.
The originally cleared Galileo NEO® (BK100033) was updated with the following modifications in the current submission:

- The Digi CCD camera module was replaced with an IDS CMOS camera module
- Galileo NEO® software was replaced with NEO Iris® Install Set 3.0.1.0 U software and configuration files
- Galileo NEO® versions of the files OiBxEngl.dll and GalileoLogo.bmp were installed to preserve Galileo NEO® branding in the User Interface and on Reports

For detailed technological characteristics of the upgraded Galileo NEO® and the NEO Iris® instrument refer to the following clearance documents: BK100033, BK170067, K183571 and BK200542.

Intended Use

Capture-CMV® is an *in vitro* qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV® is intended to be used in screening of patients for serological evidence of previous infection by CMV using manual and semi-automated methods, NEO Iris® and Galileo NEO®.

Substantial Equivalence and Comparison to the Predicate Device

Technological Characteristics	PREDICATE DEVICE: K183571 (Capture-CMV cleared for use on NEO Iris on February 4, 2019)	PROPOSED DEVICE: Capture-CMV (for use on Galileo NEO with software version 3.0.1)
Intended Use	Capture-CMV® is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV is intended to be used in screening of blood and plasma donors or patients for serological evidence of previous infection by CMV.	Capture-CMV® is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV® is intended to be used in screening of patients for serological evidence of previous infection by CMV using manual and semi-automated methods, NEO Iris® and Galileo NEO®.
Test Principle	Serum or plasma samples are added to the viral-coated wells. The samples are incubated for five minutes; during which antibodies specific for CMV proteins bind to immobilized viral proteins. Unbound immunoglobulins are washed from the wells and replaced with a suspension of anti-IgG- plus anti-IgM-coated indicator red cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized viral proteins. In the case of a positive test, the migration of the indicator red cells to the bottom of the well is impeded as the anti-IgG and anti- IgM bridges are formed between the indicator red cells and the viral-bound antibodies. As a consequence, the indicator red cells adhere over the surface of the microtitration well. In contrast, in the absence of viral antigen-antibody interactions (i.e., a negative test) the indicator red cells are not impeded during their migration, and pellet to the bottom of the well as a packed, well-defined cell button.	Serum or plasma samples are added to the viral-coated wells. The samples are incubated for five minutes; during which antibodies specific for CMV proteins bind to immobilized viral proteins. Unbound immunoglobulins are washed from the wells and replaced with a suspension of anti-IgG- plus anti-IgM-coated indicator red cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized viral proteins. In the case of a positive test, the migration of the indicator red cells to the bottom of the well is impeded as the anti-IgG and anti-IgM bridges are formed between the indicator red cells and the viral-bound antibodies. As a consequence, the indicator red cells adhere over the surface of the microtitration well. In contrast, in the absence of viral antigen-antibody interactions (i.e., a negative test) the indicator red cells are not impeded during their migration, and pellet to the bottom of the well as a packed, well-defined cell button.
Test Wells	CMV antigen from cytomegalovirus strain AS 169 grown in human foreskin fibroblast cells is inactivated and coated onto microtitration wells and dried.	CMV antigen from cytomegalovirus strain AS 169 grown in human foreskin fibroblast cells is inactivated and coated onto microtitration wells and dried.
Capture-CMV Positive Control Serum (Weak)	Human serum containing IgG antibodies to CMV viral proteins. Capture-CMV Positive Control Serum (weak) is manufactured to represent the reactivity obtained by weak CMV antibody positive donors. Weak CMV antibody positive donors have a titration endpoint of 1:2 or less. Sodium azide (0.1%) has been added as a preservative.	Human serum containing IgG antibodies to CMV viral proteins. Capture-CMV Positive Control Serum (weak) is manufactured to represent the reactivity obtained by weak CMV antibody positive donors. Weak CMV antibody positive donors have a titration endpoint of 1:2 or less. Sodium azide (0.1%) has been added as a preservative.

Technological Characteristics	PREDICATE DEVICE: K183571 (Capture-CMV cleared for use on NEO Iris on February 4, 2019)	PROPOSED DEVICE: Capture-CMV (for use on Galileo NEO with software version 3.0.1)
Capture-CMV Negative Control Serum	Human serum containing no antibodies to CMV. Sodium azide (0.1%) has been added as a preservative.	Human serum containing no antibodies to CMV. Sodium azide (0.1%) has been added as a preservative.
Capture-CMV Indicator Red Cells	A suspension of human red blood cells coated with rabbit anti-human IgG plus goat anti-human IgM molecules. The red blood cells are suspended in a buffered solution to which chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) have been added as preservatives.	A suspension of human red blood cells coated with rabbit anti-human IgG plus goat anti-human IgM molecules. The red blood cells are suspended in a buffered solution to which chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) have been added as preservatives.
Capture-LISS	A low ionic strength solution containing glycine, bromocresol purple dye and the preservative sodium azide (0.1%).	A low ionic strength solution containing glycine, bromocresol purple dye and the preservative sodium azide (0.1%).
Shelf-life	Test wells – 6 months Controls – 15 months Capture-LISS – 12 months Indicator Red Cells – 60 days	Test wells – 6 months Controls – 15 months Capture-LISS – 12 months Indicator Red Cells – 60 days
Specimen/ Sample	Serum or plasma	Serum or plasma
Test Methods	• Manual/Semi-Automated (BK950029) • Galileo (BK050050) • Galileo NEO® (BK100033[1] / BK170067[2]) • NEO Iris® (K183571[3]) 1) Capture-CMV® cleared for use on the Galileo NEO®. 2) Capture-CMV® cleared for use on the Galileo NEO® (Special 510(k) submission filed to update analyzer modifications only). 3) Capture-CMV® cleared for use on NEO Iris®	• Manual/Semi-Automated • Galileo® • Galileo NEO® • NEO Iris® • Galileo NEO® with software version 3.0.1

Performance Data and Testing – Non-Clinical

As noted in the Device Description section above, this submission describes an upgrade of the Galileo NEO® instrument, making it functionally identical to the NEO Iris®. As such, no new studies were performed. Instead, previous data supporting the original clearance of the Capture-CMV® assay on the NEO Iris® (K183571) are presented to demonstrate performance of the upgraded Galileo NEO® system.

The verification of the Capture-CMV® assay was executed under the verification plan for the NEO Iris®, in order to demonstrate equivalency with the Galileo NEO® with software version 3.0.1.

The system verification activities for NEO Iris® were performed as defined in Verification Plan 14-012-VRPLN at Immucor's facility in Norcross, GA. The verification activities included all testing performed related to the CMV assay as appropriate including assay performance for establishing equivalency. All documents generated to support the development, and operations of the system adhere to standard procedures. Testing was executed properly, in accordance with the execution and test procedure instructions. Additional and detailed information about the system verification can be found under the NEO Iris premarket notification BK180243. The results of the verification have been found acceptable to confirm safety and performance.

Performance Data and Testing – Clinical

No new clinical studies were performed as the NEO Iris® and the upgraded Galileo NEO® (software version 3.0.1) instruments are functionally identical. The data in the following tables were submitted for clearance of the NEO Iris® in K183571 and are included in the current submission to support clearance of the Capture-CMV® assay when used with the upgraded Galileo NEO® (software version 3.0.1). In these studies, the performance of the Capture-CMV® on NEO Iris® was compared with the performance of the assay on the original Galileo NEO® instrument (cleared in BK100033). For more information refer to K183571: Capture-CMV® (K183571 Letter and K183571 Summary).

In K183571 method comparison studies were performed at four clinical sites, three external sites and internally at Immucor, Inc. for donor specimens and at two external sites and internally at Immucor, Inc. for patient specimens. Specimens were tested on NEO Iris® and Galileo NEO®. Test results were evaluated for agreement between analyzers. Specimens with discordant results were further tested with a commercially available particle agglutination assay for total antibody (IgG+IgM) to CMV.

Specimen testing by sites:

Sites	Patient Specimens		
	Total	Serum	Plasma
1	26	18	8
2	0	0	0
3	195	70	125
4	280	212	68

CMV Initial Results Patient Sample N=501		Galileo NEO®	
		Positive	Negative
NEO Iris®	Positive	272	5
	Negative	0	224
CMV Resolved Results		Galileo NEO® / FDA cleared assay*	
		Positive	Negative
NEO Iris®	Positive	272	5
	Negative	0	224
Sensitivity 100.0% (98.7%, 95% 2-sided LCl)			
Specificity 97.8% (95.0%, 95% 2-sided LCl)			

*Only discordant specimens were tested with IgG/IgM FDA cleared assay. Results are for North America Market assays.

Reproducibility

The reproducibility of Capture-CMV assay on the NEO Iris® was determined using a panel of ten (10) coded samples, five (5) CMV antibody positive and five (5) CMV antibody negative, at three (3) test sites, two external sites and internally at Immucor, Inc. The samples were tested by two operators, in duplicated on two (2) runs per day for five (5) nonconsecutive days. The summary of reproducibility results by site are presented in the following table:

Concordance by Site							
Site	Total Tests	Expected Positive	Observed Positive	% Concordance (95% LCl)	Expected Negative	Observed Negative	% Concordance (95% LCl)
1	400	200	200	100.0% (98.5%)	200	200	100.0% (98.5%)
2	400	200	200	100.0% (98.5%)	200	200	100.0% (98.5%)
3	400	200	200	100.0% (98.5%)	200	199	99.5% (97.7%)
Total	1200	600	600	100.0% (98.5%)	600	599	99.8% (99.2%)

Specificity and Cross-reactivity

The following table summarizes Capture-CMV results when testing samples from subjects with the following IgG antibodies:

Category of Specimen	Number	Capture-CMV Positive
EBV (VCA) Epstein-Barr Virus (Viral Capsid Antigen)	16	0
HSV – Herpes Simplex Virus	Type I – 10 Type II – 13 IgM* – 2	0
Hepatitis A	5	1
Parvovirus B19	4	0
ANA – Anti-Nuclear Antibodies	11	1
RF – Rheumatoid Factor	10	0
VZ – Varicella Zoster	8	0
Rubella	8	0
Toxoplasma gondii	4	0

*HSV Type not specified

To ensure suitable reactivity and specificity, each assay component lot of the Capture-CMV assay is tested prior to release against sera known to contain specific antibodies to CMV viral proteins, as well as sera known to be free of such antibodies.

Conclusion

The non-clinical and clinical study data demonstrate that the Capture-CMV® assay used with Galileo NEO® instrument is as safe and effective as the predicate device.

Bibliography

1. Plapp FV, Sinor LT, Rachel JM et al. A solid phase antibody screen. Am J Clin Pathol 1984;82:719.
2. Coombs RRA, Marks J, Bedford D. Specific mixed agglutination: Mixed erythrocyte-platelet anti-globulin reactions for the detection of platelet antibodies. Br J Haematol 1956;2:84.
3. Hogman C. The principle of mixed agglutination applied to tissue culture systems. Vox Sang 1959;4:12.