February 4, 2019

Immucor, Inc.
Howard Yorek
Senior Director, Regulatory Affairs
3130 Gateway Drive
Norcross, Georgia 30071

Re: K183571
Trade/Device Name: Capture-CMV
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents
Regulatory Class: Class II
Product Code: LJO
Dated: December 14, 2018
Received: January 8, 2019

Dear Howard Yorek:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183571

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 blood and plasma donors or patients for serological evidence of previous infection by CMV.

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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Applicant Information

510(k) Owner:	Immucor, Inc.
Address:	3130 Gateway Drive Norcross, GA 30071
Telephone:	770-441-2051
Fax:	770-441-3081
Contact:	Howard Yorek
Date Prepared:	December 14, 2018

Device Information

Device Trade Name:	Capture-CMV®
Device Common Name:	CMV Antibody Screen
Device Classification Name:	Cytomegalovirus serological reagents
Device Classification:	Class II
Classification Product Code:	LJO
Regulation Number:	21 CFR 866.3175
Predicate Device:	Capture-CMV (K910003)
510(k) Number:	K183571

Device Description and Intended Use

Summary of the Test

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 IgM-coated red cells as the indicator system.

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.

Substantial Equivalence and Comparison to the Predicate Device

Technological Characteristics	Predicate Device	Proposed Device	Comparison
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 blood and plasma donors or patients for serological evidence of previous infection by CMV.	Equivalent – Indications for use add NEO Iris for diagnostic screening
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 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 test well. In contrast, in the absence of viral antigen-antibody interactions (i.e. a negative test) the indicator red cells are not	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 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 test well. In contrast, in the absence of viral antigen-antibody interactions (i.e. a negative test) the indicator red cells are not	Identical

	impeded during their migration, and pellet to the bottom of the well as a packed, well-defined cell button.	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.	Identical
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 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 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.	Identical
Capture-CMV Negative Control Serum	Human serum containing no antibodies to CMV viral proteins. Sodium azide (0.1%) has been added as a preservative.	Human serum containing no antibodies to CMV viral proteins. Sodium azide (0.1%) has been added as a preservative.	Identical
Capture-CMV Indicator Red Cells	A suspension of human red blood cells coated with rabbit anti-human IgG plus goat anti-human IgM antibodies. 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 antibodies. 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.	Identical
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%).	Identical
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	Identical
Specimen	Serum or plasma	Serum or plasma	Identical
Test Methods	Manual/Semi-automated diagnostic screening (K910003) Manual/Semi-automated donor screening (BK950029) Galileo® donor and diagnostic screening (BK050050) Galileo Neo® donor and diagnostic screening (BK100033) NEO Iris™ donor screening (BK180247)	Manual/Semi-automated diagnostic screening (K910003) Manual/Semi-automated donor screening (BK950029) Galileo® donor and diagnostic screening (BK050050) Galileo Neo® donor and diagnostic screening (BK100033) NEO Iris™ donor screening (BK180247)	Equivalent – Indications for use add NEO Iris for diagnostic screening

Performance Testing – Non-Clinical

Design verification studies and other studies were performed to demonstrate design inputs for the Capture-CMV assay on the NEO Iris were met and to demonstrate equivalence in performance between the predicate device, Capture-CMV testing on the Galileo Neo® and the proposed device, Capture-CMV testing on the NEO Iris™.

Performance Testing – Clinical

Method comparison studies were performed at three clinical sites, two external sites and internally at Immucor, Inc. 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.

CMV Initial Results Patient Samples N=501		**Galileo Neo**	
		Positive	Negative
NEO Iris	Positive	272	5
	Negative	0	224
CMV Resolved Results		**Galileo Neo / Anti-CMV PA**	
		Positive	Negative
NEO Iris	Positive	272	5
	Negative	0	224
Sensitivity 100.0% (98.7%, 95% 2-sided LCI)			
Specificity 97.8% (95.0%, 95% 2-sided LCI)			

The reproducibility of the Capture-CMV assay on 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% LCI)	Expected Negative	Observed Negative	% Concordance (95% LCI)
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%)

Conclusion

The clinical and non-clinical performance data demonstrate substantial equivalence of the NEO Iris Capture-CMV assay in terms of safety, design, performance and reproducibility compared to the predicate device.