K100433

510(k) Summary as Required by 21 CFR 807.92

Submitter: Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900

Contact Person: Robert C. Eusebio
Director Regulatory Affairs
1584 Enterprise Blvd
West Sacramento, CA 95691
(916) 374-3183

MAY 13 2010

Date Prepared: May 10, 2010

Device Trade Name: IMMULITE® 2000 CMV IgM

Common Name: Cytomegalovirus serological reagents
21 CFR 866.3175

Substantial Equivalence: K933549
VIDAS® CMV IgM assay

Device Description: IMMULITE 2000 CMV IgM is a solid-phase, enzyme labeled chemiluminescent three-step immunoassay. The solid phase (bead) is coated with inactivated, purified CMV antigen (strain AD-169 from infected cell lysates). The liquid phase consists of two reagents: 1) polyclonal goat anti-human IgG antibody in buffer, and 2) alkaline phosphatase (bovine calf intestine) conjugated to polyclonal goat anti-human IgM antibody in buffer.

In the first cycle, the patient sample and polyclonal goat anti-human IgG antibody are incubated together without the bead for 30 minutes. During this time, anti-IgG antibodies block IgG present in the patient's sample.

In the second cycle, the pretreated sample and polyclonal goat anti-human IgG antibody are transferred to the second reaction tube. Anti-IgG antibodies block the remaining IgG from the patient's sample from binding to the CMV antigen on the bead. During this time, CMV IgM in the patient sample binds to CMV antigen on the bead. Unbound sample and reagent are then removed by centrifugal washes.

In the third cycle, the enzyme conjugated polyclonal goat

anti-human IgM antibody is added to the second reaction tube. The enzyme conjugate binds to immobilized IgM to form the antibody sandwich complex. The unbound enzyme conjugate is removed by centrifugal washes. Finally, chemiluminescent substrate is added to the reaction tube and the signal is generated in proportion to the bound enzyme.

Intended Use: IMMULITE® 2000 CMV IgM is for *in vitro* diagnostic use with IMMULITE® 2000 Systems analyzers for the qualitative detection of IgM antibodies to cytomegalovirus (CMV) in human serum or plasma (EDTA or heparinized), as an aid in the diagnosis of current and recent CMV infection in individuals with signs and symptoms of CMV infection or clinical suspicion of CMV infection. This assay is not FDA cleared or approved for use in testing (screening) blood or plasma donors, neonatal screening, or for use at point-of-care facilities.

Performance characteristics for this assay have not been established in immunocompromised, immunosuppressed or organ transplant individuals.

Technological Aspects: A comparison of the device features, intended use, laboratory data and other information demonstrate that the IMMULITE® 2000 CMV IgM assay is substantially equivalent to the currently marketed bioMerieux Vitek VIDAS CMV IgM assay, as summarized in the following tables.

Table 1: Comparison of IMMULITE® with VIDAS® Assay

	IMMULITE 2000	VIDAS
Intended Use	For *in vitro* diagnostic use with IMMULITE® 2000 Systems analyzers — for the qualitative detection of IgM antibodies to cytomegalovirus (CMV) in human serum or plasma (EDTA or heparinized), as an aid in the diagnosis of current and recent CMV infection in individuals with signs and symptoms of CMV infection or clinical suspicion of CMV infection. This assay is not FDA cleared or approved for use in testing (screening) blood or plasma donors, neonatal screening, or for use at point-of-care facilities. Performance characteristics for this assay have not been established in immunocompromised, immunosuppressed or organ transplant individuals.	For *in vitro* diagnostic use with a VIDAS instrument as an automated enzyme-linked fluorescent immunoassay (ELFA) for the qualitative detection of anti-CMV IgM antibodies in human serum. It is intended to be used as an aid in the diagnosis of cytomegalovirus infection. It is not intended for use in testing (screening) blood or plasma donors.
Assay Type	Chemiluminescent enzyme IgM antibody μ-capture immunoassay	Enzyme-linked fluorescent immunoassay (ELFA)
Capture/Detection Antigen/Antibody	The solid phase is a bead coated with inactivated, purified CMV antigen (strain AD-169 from infected cell lysates). The conjugate is polyclonal goat anti-human IgM antibody conjugated to alkaline phosphatase.	The Solid Phase Receptacle is coated with CMV antigen (strain AD169). The conjugate is comprised of mouse monoclonal anti-human IgM antibodies conjugated to alkaline phosphatase.
Type of Assay	Qualitative Assay	Qualitative Assay

	IMMULITE 2000	VIDAS
Cut-Offs	Test value = ratio of signal from sample to that of signal of adjustor curve parameter P1. ≥1.1 Reactive 0.9 to < 1.1 Indeterminate <0.9 Non-reactive	Test Value Threshold = ratio of signal from sample to set of thresholds stored in the computer ≥0.90 Positive ≥0.70 to < 0.90 Equivocal <0.70 Negative
Sample Volume	10 µL	100 µL
Sample Type	Serum or plasma (EDTA or heparinized)	Serum
Cross-Reactivity	Of 197 samples tested for potential crossreactivity one rheumatoid factor (RF) sample tested reactive and one RF sample tested indeterminate.	Of 62 samples tested for potential crossreactivity, 6 yielded positive results.
Interference	Not effected by hemolysis, lipemia or icterus at test levels.	Potential hemolysis, icterus and lipemia interferences unknown as testing is not reported in package insert.

As part of the clinical study, samples from various patient populations were tested with both the IMMULITE® 2000 CMV IgM assay and the VIDAS® CMV IgM assay. A total of 636 serum samples were collected at four U.S. sites and three commercial suppliers and were tested at three U.S. sites. There were 109 retrospective samples tested where the CMV IgM + status was known. The remaining 527 samples from target enrollment groups were collected prospectively. Each sample was tested with the IMMULITE 2000 CMV IgM assay and with a commercially available CMV IgM assay (Kit A).

Comparison for Prospective Subjects*

Kit A	IMMULITE 2000 CMV IgM		
	Reactive	Indeterminate	Nonreactive
Positive	8	0	2
Equivocal	2	1	7
Negative	6	6	495

Positive Agreement: 47.1% (8/17, 95% CI: 23.0% – 72.2%)
Negative Agreement: 97.2 % (495/509, 95% CI: 95.4% – 98.5%

* *Note:* The terms "reactive", "nonreactive" and "indeterminate" (Ind) used for IMMULITE 2000 results correspond to "positive", "negative" and "equivocal" as used by other manufacturers in this context.

Comparison for Retrospective Subjects

Kit A	IMMULITE 2000 CMV IgM		
	Reactive	Indeterminate	Nonreactive
Positive	90	0	1
Equivocal	5	1	1
Negative	2	0	9

Positive Agreement: 97.8% (90/92, 95% CI: 92.4% – 99.7%)
Negative Agreement: 56.3% (9/16, 95% CI: 29.9% – 80.2%

Precision information in the product insert for the predicate CMV IgM assay shows inter-assay coefficients of variation (CV) ranging from 4.0% to 6.5% for the two controls reported. The precision of the IMMULITE 2000 CMV assay as measured by total CV ranged from 5.1% to 21.4% for the 8 samples tested.

A comparison of the device features, intended use, laboratory data and other information demonstrates that the IMMULITE® 2000 CMV IgM is substantially equivalent to the currently marketed bioMerieux Vitek VIDAS CMV IgM assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

MAY 13 2010

Siemens Healthcare Diagnostics
c/o Mr. Robert C. Eusebio
Director Regulatory Affairs
1584 Enterprise Blvd.
West Sacramento, CA 95691

Re: K100433
Trade/Device Name: IMMULITE® 2000 CMV IgM
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents.
Regulatory Class: Class II
Product Code: LKQ, JIT, JJX
Dated: February 09, 2010
Received: February 16, 2010

Dear Mr. Eusebio:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100433

Device Name: IMMULITE® 2000 CMV IgM

Indications for Use:

IMMULITE® 2000 CMV IgM is for *in vitro* diagnostic use with IMMULITE® 2000 Systems analyzers for the qualitative detection of IgM antibodies to cytomegalovirus (CMV) in human serum or plasma (EDTA or heparinized), as an aid in the diagnosis of current and recent CMV infection in individuals with signs and symptoms of CMV infection or clinical suspicion of CMV infection. This assay is not FDA cleared or approved for use in testing (screening) blood or plasma donors, neonatal screening, or for use at point-of-care facilities.

Performance characteristics for this assay have not been established in immunocompromised, immunosuppressed or organ transplant individuals.

CMV IgM Controls are assayed, bi-level controls intended for use with the IMMULITE 2000 CMV IgM assay. They are intended as an aid in monitoring day-to-day assay performance.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K100433