JAN 14 2014

SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K132739

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Garo Mimaryan, MS, RAC Senior Regulatory Affairs Specialist
Phone Number:	(914)-524-3270
Fax Number:	(914)-524-2101
E-mail Address:	garo.mimaryan@siemens.com
Date Prepared:	January 8, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 OM-MA Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 OM-MA assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 OM-MA assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys CA 125 II CalCheck 5
   Predicate 510(k) No: K102086

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. CVM 1 contains a bovine protein/buffer matrix with preservatives. CVM2, CVM3 and CVM4, contain low, intermediate and high levels of CA 125 in a bovine protein/buffer matrix with preservatives. CVMs are supplied in lyophilized form.

5. **Intended Use:**

Indication for Use:	See Indications for Use Statement below The IMMULITE® OM-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE OM-MA assay on the IMMULITE 2000 systems
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 OM-MA Calibration Verification Material (CVM) is substantially equivalent to the predicate device, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 OM-MA CVM	**Predicate Device Elecsys CA 125 II CalCheck 5**
Intended Use	The IMMULITE® OM-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE OM-MA assay on the IMMULITE 2000 systems.	The Elecsys CA 125 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 125 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only
Analyte	CA 125	Same
Form	Lyophilized	Same
Stability	Stable until the expiration date when stored refrigerated.	Same
Storage	2-8°C	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 OM-MA CVM	**Predicate Device Elecsys CA 125 II CalCheck 5**
Matrix	Bovine serum	Level 1: Equine serum Levels 2-5 : Human serum
Use	Single Use Only	Not For Single Use

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 OM-MA Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 OM-MA Calibration Verification Materials (CVMs) are stable up to 9 years when stored refrigerated at 2-8°C prior to opening.

Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) and the dose value determined from the reference calibrator curve and is summarized in Table 2.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LOPCVM1	1	1825	2555	3285
LOPCVM2	1	1825	2555	3285
LOPCVM3	1	1825	2555	3285
LOPCVM4	1	1825	2555	3285

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE OM-MA Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the Guideline acceptance criteria which require dose value of stability CVM to fall between ±10% of assigned dose for CVM levels 2 to 3 and ±11% of assigned dose for CVM level 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±10% of assigned dose for CVM levels 2 to 3 and ±11% of assigned dose for CVM level 4, then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE OM-MA CVMs are traceable to internal assigned reference calibrators prepared using OM-MA antigen stock solution and are traceable to internal material which is gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
OM-MA CVMs are 4 level materials which are a subset of 9 level OM-MA calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of OM-MA reagents and two point adjustors. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Three levels of commercially available controls and 30 samples (5 normal patient samples and 25 normal patients spiked with high patient sample) were used to validate CVM value assignments

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of nine runs and three replicates per run on nine systems and three different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges

Expected Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run, 3 different reagent kit lots and 9 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 2-500 U/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	CVM Levels	Target Mean (U/mL)	SD	Guideline ±2SD Range (U/mL)	
	CVM1	0.00	-	0.00	≤2.00
	CVM2	7.70	0.845	6.01	9.39
	CVM3	57.0	2.85	51.3	62.7
	CVM4	609	-	-	-
	(85% of CVM4 + 15% of CVM1)*	518	28.5	461	575
Assay Range	2 -500 U/mL				

*Note: CVM4 requires dilution to ensure the target value is within +10% of the top of the reportable range of the assay.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

9. Conclusion:

OM-MA Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys CA 125 II CalCheck 5. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 OM-MA Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

JAN 14 2014

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510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K132739

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Garo Mimaryan, MS, RAC Senior Regulatory Affairs Specialist
Phone Number:	(914)-524-3270
Fax Number:	(914)-524-2101
E-mail Address:	garo.mimaryan@siemens.com
Date Prepared:	January 8, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 BR-MA Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 BR-MA assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 BR-MA assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**
Predicate 510(k) No: Elecsys CA 15-3 II CalCheck 5
K122242

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. CVM 1 contains a bovine serum matrix with preservatives. CVM2. CVM3 and CVM4 contain low, intermediate and high levels of human source CA 15-3 in a bovine serum matrix with preservatives. CVMs are supplied frozen in liquid form. In addition to using the CVM at their manufactured concentrations, alternate concentrations may be obtained by accurately diluting the assay-specific calibrator levels with each other.

5. **Intended Use:**

Indication for Use:	See Indications for Use Statement below The IMMULITE® BR-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE BR-MA assay on the IMMULITE 2000 systems
Special Conditions for Use Statement(s):	
Special Instrument Requirements:	For prescription use only

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** IMMULITE® 2000 Systems

A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 BR-MA Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE 2000 BR-MA CVM**	Predicate Device : **Elecsys CA 15-3 II CalCheck 5**
Intended Use	The IMMULITE® BR-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE BR-MA assay on the IMMULITE 2000 systems	The Elecsys CA 15-3 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 15-3 II reagent on the indicated Elecsys and cobas e immunoassay analyzers. For in vitro diagnostic use only.
Analyte	CA 15-3	Same

	DIFFERENCES	
	Candidate Device **IMMULITE 2000 BR-MA CVM**	Predicate Device : **Elecsys CA 15-3 II CalCheck 5**
Form	Liquid	Lyophilized
Matrix	Bovine serum	Level 1: Equine serum matrix Levels 2-5 : Human serum matrix
Stability	Stable until the expiration date when stored frozen	Stable until the expiration date when stored refrigerated.
Storage	-20°C	2-8°C
Use	Single Use Only	Not For Single Use

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 BR-MA Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 BR-MA Calibration Verification Materials (CVMs) are stable up to 4.5 years when stored refrigerated at -20°C prior to opening.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) and the dose value determined from the reference calibrator curve and is summarized in Table 2.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LBRCVM1	1	730	912	1095
LBRCVM2	1	730	912	1095
LBRCVM3	1	730	912	1095
LBRCVM4	1	730	912	1095

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE BR-MA Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the Guideline acceptance criteria which require dose value of stability CVM to fall between ±15% of assigned dose for CVM level 2 and ±10% of assigned dose for CVM levels 3 and 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±15% of assigned dose for CVM level 2 and ±10% of assigned dose for CVM levels 3 and 4, then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE BR-MA CVMs are traceable to internal assigned reference calibrators prepared using BR-MA antigen stock solution and are traceable to internal material which is gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures

Value Assignment:
BR-MA CVMs are 4 level materials which are a subset of 7 level BR-MA calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of BR-MA reagents and two point adjustors. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Six levels of commercially available controls and 30 samples (5 normal patient samples and 25 spiked patient samples) were used to validate CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of 9 runs and three replicates per run on 6 systems and 3 different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges.

Expected Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run, 3 different reagent kit lots and 6 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 1-300 IU/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	**Level**	**Target Mean (U/mL)**	**SD**	**Guideline ±2SD Range (U/mL)**	
	1	0.00	-	0.00	≤1.00
	2	18.8	1.4	16.0	21.6
	3	165	8.25	149	182
	4	291	14.5	262	320
Assay Range	1 -300 U/mL				

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

9. **Conclusion:**
BR-MA Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys CA 15-3 II CalCheck 5. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device. The IMMULITE® 2000 BR-MA Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

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SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k132739

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
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Fax Number:	(914)-524-2101
E-mail Address:	garo.mimaryan@siemens.com
Date Prepared:	January 8, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 AFP Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 AFP assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 AFP assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**
Predicate 510(k) No: IMMULITE/IMMULITE 1000 Third Generation PSA CVM
K122534

4. **Device Description:** The Calibration Verification Material (CVM) contains One set of four vials each 3mL. CVM1 contain bovine serum matrix with preservatives. CVM2, CVM 3 and CVM4 contain low, intermediate and high levels of human source AFP respectively, in a bovine serum matrix with preservatives. CVMs are supplied frozen in a liquid form.

5. **Intended Use:** See Indications for Use Statement below

Indication for Use:	The IMMULITE® 2000 AFP Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of AFP antigen.
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 AFP Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE 2000 AFP CVM**	**Predicate Device** **IMMULITE/IMMULITE 1000 Third Generation PSA CVM**
Intended Use	The IMMULITE® 2000 AFP Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of AFP antigen.	The IMMULITE®/IMMULITE 1000 Third Generation PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen.
Form	Liquid	Same
stability	Stable until the expiration date when stored frozen	Same
Storage	-20°C	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device **IMMULITE 2000 AFP CVM**	**Predicate Device** **IMMULITE/IMMULITE 1000 Third Generation PSA CVM**
Analyte	AFP	PSA
Matrix	Bovine serum	Chicken serum
Assay Range	0.2 –300 IU/mL	0.015 – 20 ng/mL

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 AFP Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 AFP Calibration Verification Materials (CVMs) are stable up to 3.5 years when stored refrigerated at -20°C prior to opening.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) and the dose value determined from the reference calibrator curve and is summarized in Table 2.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LAPCVM1	1	912	1095	1460
LAPCVM2	1	912	1095	1460
LAPCVM3	1	912	1095	1460
LAPCVM4	1	912	195	1460

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE AFP Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the Guideline acceptance criteria which require dose value of stability CVM to fall between ±15% of assigned dose for CVM levels 2 and ±10% of assigned dose for CVM levels 3 and 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±15% of assigned dose for CVM levels 2 and ±10% of assigned dose for CVMs 3 and 4, then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE AFP CVMs are traceable to WHO 1st IS 72/225 and are manufactured using qualified materials and measurement procedures.

Value Assignment:
IMMULITE® 2000 AFP (Alpha-fetoprotein) Calibration Verification Materials are 4 level materials which are a subset of 9 level AFP calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of AFP reagents and two point adjustors. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Nine levels of commercially available controls and 61 samples including amniotic fluid samples, pregnancy trimester samples, normal patient samples and spiked AFP samples were used to validate CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges

Expected Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run. 3 different reagent kit lots and 5 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 0.2 -300 IU/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	**CVM Level**	**Target Mean (IU/mL)**	**SD**	**Guideline ±2SD Range (IU/mL)**	
	CVM1	0.00	-	0.00	≤0.20
	CVM2	3.03	0.225	2.58	3.48
	CVM3	47.9	2.4	43.1	52.7
	CVM4	413	-	-	-
	(75% CVM4 + 25% CVM1)	310	15.5	279	341
Assay Range	0.2 -300 IU/mL				

*Note: CVM4 requires dilution to ensure that the target value is within the +10% of the top of the reportable range of the assay.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

9. **Conclusion:**

IMMULITE® 2000 AFP (Alpha-fetoprotein) Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed IMMULITE/IMMULITE 1000 Third Generation PSA CVM. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 AFP Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics Inc.
c/o Mr. Garo Mimaryan
Technical Regulatory Affairs Specialist III
511 Benedict Avenue
Tarrytown, NY 10591

January 14, 2014

Re: k132739
Trade/Device Name: IMMULITE® 2000 AFP Calibration Verification Material
IMMULITE® 2000 BR-MA Calibration Verification Material
IMMULITE® 2000 OM-MA Calibration Verification Material
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I
Product Code: JJX
Dated: December 13, 2013
Received: December 16, 2013

Dear Mr. Mimaryan:

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); 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), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology 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 on last page.

510(k) Number *(if known)*
K132739

Device Name
IMMULITE® 2000 AFP Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® 2000 AFP Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of AFP antigen.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Stafford -S

PSC Publishing Services (301) 443-6740 EF

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 on last page.

510(k) Number *(if known)*
K132739

Device Name
IMMULITE® 2000 BR-MA Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® BR-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE BR-MA assay on the IMMULITE 2000 systems

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)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*
K132739

Device Name
IMMULITE® 2000 OM-MA Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® OM-MA Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE OM-MA assay on the IMMULITE 2000 systems

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)

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