SIEMENS

JUL 09 2014

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: k141444

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045
Contact Person:	Donna Velasquez Regulatory Technical Specialist
Phone Number:	(310)-645-8200 x7403
Fax Number:	(310)-645-9999
E-mail Address:	donna.velasquez@siemens.com
Date Prepared:	May 30, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Cortisol Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 Cortisol assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Cortisol 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**: IMMULITE® 2000 Total T3 Calibration Verification Material (CVM)

Predicate 510(k) No: K133124

4. **Device Description:** The IMMULITE® 2000 Cortisol Calibration Verification Material (CVM) contains one set of four vials each 3mL. CVM1 contains human serum with preservatives and CVM2, CVM3, and CVM4 contain various levels of cortisol in human serum with preservatives.

5. **Intended Use:**

Indication for Use: See Indications for Use Statement below
The IMMULITE® Cortisol Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Cortisol 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 Cortisol 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 Cortisol CVM	**Predicate Device IMMULITE 2000 Total T3 CVM**
Intended Use	The IMMULITE® Cortisol Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Cortisol assay on the IMMULITE 2000 systems.	The IMMULITE® Total T3 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Total T3 assay on the IMMULITE 2000 systems
Storage	-20°C	Same
Form	Liquid	Same
Stability	Stable unopened until the expiration date	Same
Levels	4	Same
Matrix	Human Serum with preservatives	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 Cortisol CVM	**Predicate Device IMMULITE 2000 Total T4 CVM**
Analyte	Cortisol	Total T3

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 real-time shelf life and open component (in-use or open vial) claim for the IMMULITE 2000 Cortisol 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 Calibration Verification Materials are stable up to 14 months when stored at -20°C prior to opening and stable for 8 hours at ambient or room temperature (15-25°C) after opening.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. The stability calibrators/CVMs are run in duplicate (as a minimum) at the time points shown in **Table 2,** and the dose value is determined from the reference calibrator curve.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LCOCVM1	1	182	365	425
LCOCVM2	1	182	365	425
LCOCVM3	1	182	365	425
LCOCVM4	1	182	365	425

For Open Component testing, the results were determined from a 2-point adjustment. Using IMMULITE 2000 Cortisol (L2KCO) kit lot 362, lot 090 CVMs were tested at 2-hourly intervals for up to 9 hours at ambient or room temperature (15-25°C) conditions.

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the Cortisol Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of guideline acceptance criteria which require dose value of stability calibrators/CVM to fall between ±20% of assigned dose for CVM level 2, ±15% of assigned dose for level 3 and ±19% of assigned dose for level 4. Part 2 review limits criteria which require dose value of the controls to be within 2 Standard Deviations (SD) of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±20% for level 2, ±15% of assigned dose for level 3 and within ±19% of assigned dose for level 4, then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE Cortisol CVMs are traceable to an internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE Cortisol CVMs are 4 level materials which are a subset of 8 level Cortisol calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Cortisol reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. 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. Six levels of commercially available controls and 25 patient serum samples, 3 spiked normal serum samples and 5 normal serum samples were used to validate calibrator/CVM value assignments.

Expected Values/Target 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 8 IMMULITE 2000 systems. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The target values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 1 to 50 g/dL. The target values in **Table 3** can be considered as guidelines.

Table 3: Analyte Target Range Values

Analyte target levels	CVM Level	*Target Mean g/dL)	Standard Deviation (SD)	Guideline ±2SD Range	
	LCOCVM1	0.00	-	0.	1.0
	LCOCVM2	4.54	0.455	3.	5.45
	LCOCVM3	18.7	1.4	15	21.5
	LCOCVM4	54.5	5.2	44	64.9
Assay Range	1 to 50 g/dL				

*Note: when CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software. If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

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

8. Conclusion:

The IMMULITE® 2000 Cortisol Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. 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 Cortisol 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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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: k141444

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045
Contact Person:	Donna Velasquez Regulatory Technical Specialist
Phone Number:	(310) 645-8200 x7403
Fax Number:	(310) 645-9999
E-mail Address:	donna.velasquez@siemens.com
Date Prepared:	May 30, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Folic Acid Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 Folic Acid assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Folic Acid 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** — IMMULITE 2000 DHEA-SO4 Calibration Verification Material (CVM)

Predicate 510(k) No: K140258

4. **Device Description:** The IMMULITE® 2000 Folic Acid Calibration Verification Material (CVM) contains one set of four vials, 3mL (CVM1) each, when reconstituted. CVM1 contains a lyophilized human albumin based matrix with preservatives. CVM2, CVM3, and CVM4 contain various levels of lyophilized folic acid in human albumin based matrix with preservatives.

5. **Intended Use:**

See Indications for Use Statement below

Indication for Use:	The IMMULITE® Folic Acid Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Folic Acid 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 Folic Acid 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 Folic Acid CVM	**Predicate Device IMMULITE 2000 DHEA-SO4 CVM**
Intended Use	The IMMULITE® Folic Acid Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Folic Acid assay on the IMMULITE 2000 systems	The IMMULITE® DHEA-SO4 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE DHEA-SO4 assay on the IMMULITE 2000 systems
Form	Lyophilized	Same
Levels	4	Same
Stability	Stable unopened until the expiration date	Same
Storage	-20°C	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 Folic Acid CVM	**Predicate Device IMMULITE 2000 DHEA-SO4 CVM**
Analyte	Folic Acid	DHEA-SO4
Matrix	Human Albumin with preservatives	Human Serum with Preservatives

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 real-time shelf life and open component (in-use or open vial) claim for the IMMULITE 2000 Folic Acid 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 Calibration Verification Materials are stable up to 3.5 years when stored at -20°C prior to opening, and for 8 hours at ambient or room temperature (15-25°C) after reconstitution.

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) at the time points shown in **Table 2** and the dose value determined from the reference calibrator curve.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LFOCVM1	1	912	1095	1280
LFOCVM2	1	912	1095	1280
LFOCVM3	1	912	1095	1280
LFOCVM4	1	912	1095	1280

For Open Component testing, the results were determined from a 2-point adjustment. Using IMMULITE 2000 Folic Acid (L2KFO) kit lot 446, lot 090B Folic Acid CVMs were tested at 2-hourly intervals for up to 9 hours at ambient or room temperature (15-25°C) conditions.

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE Folic Acid Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of guideline acceptance criteria which require dose value of stability CVMs to fall between ±15% of the assigned dose for CVM level 2, within ±10% of the assigned dose for level 3 and within ±12% of assigned dose for CVM level 4. Part 2 review limits criteria which require dose value of the controls to be within 2 Standard Deviations (SD) of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±15% of the assigned dose for CVM level 2, within ±10% of the assigned dose for level 3 and within ±12% of assigned dose for CVM level 4 then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE Folic Acid CVMs are traceable to an internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE Folic Acid CVMs are 4 level materials which are a subset of 8 level Folic Acid calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Folic Acid reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. 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. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The controls must fall within their target ranges. Six levels of commercially available controls and 14 patient serum samples, 12 fasting samples were used to validate calibrator/CVM value assignments.

Expected Values/Target Values/Reference Range:
The CVMs are manufactured using qualified materials and measurement procedures. The Folic Acid CVMs were tested on 27 replicates in total comprised of 9 runs and 3 replicates per run on 6 IMMULITE 2000 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. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected assay range is 1 to 24 ng/mL. The target values in **Table 3** can be considered as guidelines.

Table 3: Analyte Target Range Levels

Analyte target levels	CVM Level	*Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/mL)	
	LFOCVM1	0.00	-	0.00	1.0
	LFOCVM2	3.11	0.28	2.55	3.67
	LFOCVM3	12.4	0.75	10.9	13.9
	LFOCVM4	26.3	1.6	23.1	29.5
Assay Range	1 to 24 ng/mL				

*Note: when CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software. If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

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

8. Conclusion:

The IMMULITE® 2000 Folic Acid Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. 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 Folic Acid 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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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: k141444

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045
Contact Person:	Donna Velasquez Regulatory Technical Specialist
Phone Number:	(310)-645-8200 x7403
Fax Number:	(310)-645-9999
E-mail Address:	donna.velasquez@siemens.com
Date Prepared:	May 30, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Vitamin B12 Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE 2000 Vitamin B12
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Vitamin B12 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® 2000 DHEA-SO4 Calibration Verification Material K140258

4. **Device Description:** IMMULITE® 2000 Vitamin B12 Calibration Verification Material (CVM) contains one set of four vials, 3 mL each, when reconstituted. CVM1 contains a lyophilized human albumin-based matrix with preservatives. CVM2, CVM3, and CVM4 contain various levels of lyophilized Vitamin B12 in human albumin-based matrix with preservatives.

5. **Intended Use:**

Indication for Use:	See Indications for Use Statement below The IMMULITE® Vitamin B12 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of the IMMULITE Vitamin B12 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 Vitamin B12 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 Vitamin B12 CVM	**Predicate Device IMMULITE 2000 DHEA-SO4 CVM**
Intended Use	The IMMULITE® Vitamin B12 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Vitamin B12 assay on the IMMULITE 2000 systems.	The IMMULITE® DHEA-SO4 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE DHEA-SO4 assay on the IMMULITE 2000 systems
Form	Lyophilized	Same
Stability	Stable unopened until the expiration date	Same
Storage	-20°C	Same
Levels	4	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 Vitamin B12 CVM	**Predicate Device IMMULITE 2000 DHEA-SO4 CVM**
Analyte	Vitamin B12	DHEA-SO4
Matrix	Human Albumin with preservatives	Human Serum with preservatives

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 real-time shelf life and open component (in-use or open vial) claim for the IMMULITE 2000 Vitamin B12 CVM to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 69 months when stored at -20°C prior to opening and stable for 8 hours at room (ambient) temperature (15-25°C) after reconstitution.

Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. As summarized in **Table 2**, the testing was run in duplicate (at the minimum) and contains time-points at which the testing was performed.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Months)			
LVBCVM1	0	67	68	69
LVBCVM2	0	67	68	69
LVBCVM3	0	67	68	69
LVBCVM4	0	67	68	69

For Open Component testing, the results were determined from a 2-point adjustment. Using IMMULITE 2000 Vitamin B12 (L2KVB) kit lot 467, lot 108 Vitamin B12 CVMs were tested at 2-hourly intervals for up to 9 hours at ambient or room temperature (15-25°C) conditions.

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE Vitamin B12 Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±10% of assigned dose for CVM level 2 and level 3 and within ±21% 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% for level 2 and level 3 and ±21% for level 4, then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE Vitamin B12 CVMs are traceable to an internal standard. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE® 2000 Vitamin B12 CVMs are 4 level materials which are a subset of 8 level Vitamin B12 calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Vitamin B12 reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. 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 and controls using the assigned CVM values. Eight levels of commercially available controls and 21 patient serum samples were used to validate CVM value assignments.

Expected Values/Target Values/Reference Range:

The Vitamin B12 CVMs were tested on 24 replicates in total comprised of 12 runs and 2 replicates per run, 3 IMMULITE 2000 and 5 IMMULITE/IMMULITE 1000 systems and 4 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 and controls using the assigned CVM values. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected assay range is 150 to 1000 pg/mL. The target values in **Table 3** can be considered as guidelines.

Table 3: Analyte Target Range Levels

Analyte target levels	Level	*Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/mL)	
	LVBCVM1	0.00	-	0.00	150
	LVBCVM2	234	23.5	187	281
	LVBCVM3	579	34.5	510	648
	LVBCVM4	1144	194.5	755	1533
Assay Range	150 to 1000 pg/mL				

*Note: when CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software. If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

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:

The IMMULITE® 2000 Vitamin B12 Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. 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 Vitamin B12 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

July 9, 2014

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
C/O DONNA VELASQUEZ
REGULATORY TECHNICAL SPECIALIST
5210 PACIFIC CONCURSE DRIVE
LOS ANGELES CA 90045

Re: k141444
Trade/Device Name: IMMULITE® 2000 Cortisol Calibration Verification Material
IMMULITE® 2000 Folic Acid Calibration Verification Material
IMMULITE® 2000 Vitamin B12 Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: June 3, 2014
Received: June 5, 2014

Dear Donna Velasquez:

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 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" (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 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 yours,

Courtney H. Lias -S

Courtney H. Lias
Director
Division of Chemistry and Toxicology 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)*
k141444

Device Name
IMMULITE® 2000 Cortisol Calibration Verification Material
IMMULITE® 2000 Folic Acid Calibration Verification Material
IMMULITE® 2000 Vitamin B12 Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® Cortisol Calibration Verification Material is for in vitro diagnostic use in the verification of calibration of the IMMULITE Cortisol assay on the IMMULITE 2000 systems.

The IMMULITE® Folic Acid Calibration Verification Material is for in vitro diagnostic use in the verification of calibration of the IMMULITE Folic Acid assay on the IMMULITE 2000 systems.

The IMMULITE® Vitamin B12 Calibration Verification Material is for in vitro diagnostic use in the verification of calibration of the IMMULITE Vitamin B12 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)

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)*

Yung W. Chan -S

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