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: K132391

SEP 2 0 2013

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Garo Mimaryan, MS, RAC Technical Regulatory Affairs Specialist III
Phone Number:	(914)-524-3270
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Date Prepared:	September 16, 2013

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Anti-TG Ab Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 Anti-TG assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Anti-TG Ab 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 Anti-TG CalCheck
   Predicate 510(k) No: K020369
4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. LTGCVM1 contains human serum/ buffer matrix with preservatives. LTGCVM2, LTGCVM3 and LTGCVM4 contain low, intermediate and high levels of Anti-TG Ab respectively, in human serum/ buffer matrix matrix with preservatives.

5. **Intended Use:** See Indications for Use Statement below
   Indication for Use: The IMMULITE® Anti-TG Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TG Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.

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 Anti-TG Ab Calibration Verification Material (CVM) is substantially equivalent to the predicate device, Elecsys Anti-TG CalCheck, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE 2000 Anti-TG Ab CVM**	**Predicate Device** **Elecsys Anti-Tg CalCheck**
Intended Use	The IMMULITE® Anti-TG Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TG Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.	The Elecsys Anti-Tg CalCheck is for use in the verification of the calibration established by the Elecsys Anti-Tg reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Anti-TG Ab	Anti-Tg
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum
stability	Stable until the expiration date when stored refrigerated.	Stable until the expiration date when stored refrigerated.
Storage	2-8°C	2-8°C

	DIFFERENCES	
	Candidate Device **IMMULITE 2000 Anti-TG Ab CVM**	**Predicate Device** **Elecsys Anti-Tg CalCheck**
Levels	4	3
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 Anti-TG Ab 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 Anti-TG Ab Calibration Verification Materials (CVMs) are stable up to 7 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)			
LTGCVM1	1	182	365	548
LTGCVM2	1	182	365	548
LTGCVM3	1	182	365	548
LTGCVM4	1	182	365	548

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE 2000 Anti-TG Ab Calibration Verification Material (CVM) consists of 2 parts. Part 1 consists of the Guideline Acceptance Criteria which requires the dose value stability CVM to fall between ±15% of the assigned dose. Part 2 consists of the Review Limits Acceptance Criteria which requires the dose value of the controls to be within 2SD of the control target value generated from the stability calibrator curve. If the result is not within the acceptable dose range of ±15%, then additional data review is performed using the part 2 acceptance criterion.

Traceability:
The IMMULITE® 2000 Anti-TG Ab CVMs are traceable to WHO 1st IRP 65/93. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE Anti-TG Ab (Anti-Thyroglobulin antibody) CVMs are 4 level materials which are a subset of 8 level Anti-TG Ab calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Anti-TG Ab reagents and two point adjustors.
The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using Anti-TG antibody stock and are traceable to WHO 1st IRP 65/93. 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. Two levels of commercially available controls, and 30 patient samples (10 spiked normal patients samples, two patient samples and 18 spiked samples) are 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 seven IMMULITE 2000 systems and five 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. 5 different reagent kit lots and 7 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 20 -3000 IU/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	**Level**	**Target Mean (IU/mL)**	**SD**	**Guideline ±2SD Range (IU/mL)**	
	1	0.00	-	0.00	≤20.00
	2	73.5	-	-	-
	50% CVM1	36.8	2.75	31.3	42.3
	50% CVM2				
	3	452	34	384	520
	4	3130	234.75	2661	3600
Assay Range	20 -3000 IU/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:**

The IMMULITE® 2000 Anti-TG Ab (Anti-Thyroglobulin antibody) 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 Anti-Tg CalCheck. 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, Elecsys Anti-TG CalCheck, The IMMULITE® 2000 Anti-TG Ab 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: K132391

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Garo Mimaryan, MS, RAC Technical Regulatory Affairs Specialist III
Phone Number:	(914)-524-3270
Fax Number:	(914)-524-2101
E-mail Address:	garo.mimaryan@siemens.com
Date Prepared:	September 16, 2013

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Anti-TPO Ab Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 Anti-TPO assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Anti-TPO Ab 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 Anti-TPO CalCheck
   Predicate 510(k) No: K001014
4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. LTOCVM1 contains human serum/ buffer matrix with preservatives. LTOCVM2, LTOCVM3 and LTOCVM4 contain low, intermediate and high levels of Anti-TPO Ab respectively, in human serum/ buffer matrix matrix with preservatives.
5. **Intended Use:** See Indications for Use Statement below
   Indication for Use: The IMMULITE® Anti-TPO Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TPO Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.

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 Anti-TPO Ab Calibration Verification Material (CVM) is substantially equivalent to the predicate device, Elecsys Anti-TPO CalCheck, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE 2000 Anti-TPO Ab CVM**	**Predicate Device** **Elecsys Anti-TPO CalCheck**
Intended Use	The IMMULITE® Anti-TPO Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TPO Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.	The Elecsys Anti-TPO CalCheck is for use in the verification of the calibration established by the Elecsys Anti-TPO reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	Anti-TPO Ab	Anti-TPO
Form	Lyophilized	Lyophilized
Matrix	Human serum	Human serum
Stability	Stable until the expiration date when stored refrigerated.	Stable until the expiration date when stored refrigerated.
Storage	2-8°C	2-8°C

	DIFFERENCES	
	Candidate Device **IMMULITE 2000 Anti-TPO Ab CVM**	**Predicate Device** **Elecsys Anti-TPO CalCheck**
Levels	4	3
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 Anti-TPO Ab 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 Anti-TPO Ab 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)			
LTOCVM1	1	2555	2920	3285
LTOCVM2	1	2555	2920	3285
LTOCVM3	1	2555	2920	3285
LTOCVM4	1	2555	2920	3285

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE 2000 Anti-TPO Ab Calibration Verification Material (CVM) consists of 2 parts. Part 1 consists of the Guideline Acceptance Criteria which requires the dose value stability CVM to fall between ±25% of the assigned dose for CVM level 2 and ±15% of assigned dose for CVM levels 3 and 4. Part 2 consists of the Review Limits Acceptance Criteria which requires the dose value of the controls to be within 2SD of the control target value generated from the stability calibrator curve. If the result is not within the acceptable dose range of ±25% for level 2 and ±15% for levels 3 and 4, then additional data review is performed using the part 2 acceptance criterion.

Traceability:
The IMMULITE Anti-TPO Ab CVMs are traceable to WHO 1st IRP 66/387. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
Anti-TPO Ab (Anti-Thyroid Peroxidase Antibody) CVMs are 4 level materials which are a subset of 7 level Anti-TPO Ab calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Anti-TPO Ab reagents and two point adjustors. The assigned reference calibrators are prepared using Anti-TPO antibody stock and are traceable to WHO 1st IRP 66/387. 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. Two levels of commercially available controls, and 30 patient samples (5 patient samples and 25 spiked samples) are 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 five IMMULITE 2000 systems and four 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. 4 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 10-1000 IU/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	**Level**	**Target Mean (IU/mL)**	**SD**	**Guideline ±2SD Range (IU/mL)**	
	1	0.00	-	0.00	≤10.00
	2	34.1	3.4	27.3	40.9
	3	281	21	239	323
	4	950	71.25	808	1093
Assay Range	10 -1000 IU/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:**

Anti-TPO Ab (Anti-Thyroid Peroxidase Antibody) 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 Anti-TPO CalCheck. 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, Elecsys Anti-TPO CalCheck, The IMMULITE® 2000 Anti-TPO Ab 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: K132391

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Garo Mimaryan, MS, RAC Technical Regulatory Affairs Specialist III
Phone Number:	(914)-524-3270
Fax Number:	(914)-524-2101
E-mail Address:	garo.mimaryan@siemens.com
Date Prepared:	September 16, 2013

2. **Device Name**

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

	ADVIA Centaur® Intact PTH Master Curve Material (MCM)
Predicate 510(k) No:	K020217

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. LTYCVM1 in horse serum matrix with preservatives. LTYCVM2, LTYCVM3 and LTYCVM4 contain low, intermediate and high levels of Thyroglobulin respectively, in horse serum matrix with preservatives.

5. **Intended Use:**

	See Indications for Use Statement below
Indication for Use:	The IMMULITE® Thyroglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Thyroglobulin assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.
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 Thyroglobulin Calibration Verification Material (CVM) is substantially equivalent to the predicate device, ADVIA Centaur® Intact PTH Master Curve Material, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE® 2000 Thyroglobulin Calibration Verification Material**	**Predicate Device** **ADVIA Centaur® Intact PTH Master Curve Material**
Intended Use	The IMMULITE® Thyroglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Thyroglobulin assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.	For *in vitro* diagnostic use for evaluating the ADVIA Centaur® Intact PTH assays. This material is intended to be run singly as unknown samples after a two-point calibration has been performed on the system.
Form	Lyophilized	Lyophilized
Matrix	Equine Serum	Equine Serum
Use	Single Use Only	Single Use Only

	DIFFERENCES	
	Candidate Device **IMMULITE 2000 Thyroglobulin Calibration Verification Material (CVM)**	**Predicate Device** **ADVIA Centaur® Intact PTH Master Curve Material (MCM)**
Analyte	Thyroglobulin	Intact PTH
Levels	4	7
Stability	Stable until the expiration date when stored refrigerated.	Stable until the expiration date when stored frozen.
Storage	2-8°C	-20°C

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 Thyroglobulin 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 Thyroglobulin Calibration Verification Materials (CVMs) are stable up to 6 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)			
LTYCVM1	1	1825	2190	3285
LTYCVM2	1	1825	2190	3285
LTYCVM3	1	1825	2190	3285
LTYCVM4	1	1825	2190	3285

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE 2000 Anti-TG Ab Calibration Verification Material (CVM) consists of 2 parts. Part 1 consists of the Guideline Acceptance Criteria which requires the dose value stability CVM to fall between ±10%. Part 2 consists of the Review Limits Acceptance Criteria which requires the dose value of the controls to be within 2SD of the control target value generated from the stability calibrator curve. If the result is not within the acceptable dose range of ±10%, then additional data review is performed using the part 2 acceptance criterion.

Traceability:
The IMMULITE Thyroglobulin CVMs are traceable to Certified Reference Material from human thyroglobulin (BCR 457) in terms of the Institute of Reference Materials and Measurements of the European Commission (formerly the Community Bureau of Reference. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
Thyroglobulin CVMs are 4 level materials which are a subset of 9 level Thyroglobulin calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Thyroglobulin reagents and two point adjustors. The IMMULITE Thyroglobulin CVMs are traceable to Certified Reference Material from human thyroglobulin (BCR 457) in terms of the Institute of Reference Materials and Measurements of the European Commission (formerly the Community Bureau of Reference. 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 patient samples (5 normal patients samples and 25 spiked samples) are 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 four IMMULITE 2000 systems and four 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. 4 different reagent kit lots and 4 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 02-300 NG/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Target Values

Analyte target levels	**Level**	**Target Mean (ng/mL)**	**SD**	**Guideline ±2SD Range (ng/mL)**	
	1	0.00		0.00	≤20.0
	2	9.10	0.5	8.10	10.1
	3	36.2	2.15	31.9	40.5
	4	430	-	-	-
	30% CVM1	301			
	70% CVM4		21	259	343
Assay Range	0.2 -300 ng/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:**

Thyroglobulin 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 ADVIA Centaur® Intact PTH Master Curve Material. 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, ADVIA Centaur® Intact PTH Master Curve Material, The IMMULITE® 2000 Thyroglobulin 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 10591-5097

September 20, 2013

Re: K132391
Trade/Device Name: IMMULITE® 2000 Anti-TG Ab Calibration Verification Material;
IMMULITE® 2000 Anti-TPO Ab Calibration Verification Material;
IMMULITE® 2000 Thyroglobulin 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: July 31, 2013
Received: August 1, 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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

Maria M. Chan -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132391

Device Name
IMMULITE® 2000 Anti-TG Ab Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® Anti-TG Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TG Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.

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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FOR FDA USE ONLY

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

Maria M. Chan -S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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510(k) Number *(if known)*
K132391

Device Name
IMMULITE® 2000 Thyroglobulin Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® Thyroglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Thyroglobulin assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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510(k) Number *(if known)*
K132391

Device Name
IMMULITE® 2000 Anti-TPO Ab Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® Anti-TPO Ab Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Anti-TPO Ab assay on the IMMULITE 2000 systems as indicated in the CVM Package Insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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