K110586

OCT 14 2011

510(k) Summary

Submitter information

Contact person: Neil Parker
Senior Regulatory Affairs Specialist

Address: Siemens Healthcare Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Phone: 914-524-2477
914-524-2500 (fax)

Date summary prepared: February 28, 2011

Device Trade or Proprietary Names:

ADVIA Centaur Vitamin D Total Assay

ADVIA Centaur Vitamin D Total calibrators

ADVIA Centaur Vitamin D Total QC

ADVIA Centaur Vitamin D Total Master Curve Material

Device Common/Usual Name or Classification Name:

Vitamin D Test System
Calibrator
Quality Control Material (Assayed and Unassayed)

Classification Number / Class:

21 CFR 862.1825 – Vitamin D Test System - Class II
21 CFR 862.1150 – Calibrator - Class II
21 CFR 862.1660 – Quality Control Material (Assayed and Unassayed) – Class I

Product code:

MRG – Vitamin D Test system
JIT – Calibrator, Secondary
JJX – single (specified) Analyte Controls (Assayed and Unassayed)

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: _____

Assay Predicate Device (including calibrators and controls):

	Predicate Device
Device Name	IDS 25-Hydroxy Vitamin D EIA
Common name	Vitamin D Test System
510(k) Number	K021163
Manufacturer	Immunodiagnostic Systems Ltd (IDS Ltd)

Master Curve Material Predicate Device

	Predicate Device
Device Name	The VALIDATE Thyroid Calibration Verification Test Set
Common name	single (specified) Analyte Controls (Assayed and Unassayed)
510(k) Number	K062501
Manufacturer	Maine Standards Company

Device Description:

The ADVIA Centaur Vitamin D Total assay is a one-pass 18 minute competitive immunoassay that uses an anti-fluorescein labeled (FITC) monoclonal antibody covalently bound to paramagnetic particles (PMP), one monoclonal antibody labeled with acridium ester (AE), and a Vitamin D analog labeled with fluorescein. An inverse relationship exists between the amount of Vitamin D present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Statements of Intended Use:

The ADVIA Centaur Vitamin D Total (VitD) assay is for the in vitro diagnostic use in the quantitative determination of total 25 (OH) vitamin D in human serum and plasma (EDTA, lithium heparin, sodium heparin) using the ADVIA Centaur XP system. The ADVIA Centaur VitD assay is intended as an aid in the determination of vitamin D sufficiency.

The ADVIA Centaur Vitamin D Total (VitD) Calibrators is for *in vitro* diagnostic use in calibrating ADVIA Centaur® systems Vitamin D Total (VitD) assay.

The ADVIA Centaur Vitamin D Total (VitD) QC is for *in vitro* diagnostic use to monitor the precision and accuracy of the ADVIA Centaur® VitD assay on the ADVIA Centaur systems.

The ADVIA Centaur® Vitamin D Total (VitD) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur VitD assay.

Comparisons to the Predicate Devices:

Assay Similarities

Items	ADVIA Centaur Vitamin D Total assay	IDS 25-OH Vitamin D EIA assay (Predicate Device) k021163
	Similarity	
Intended Use/Indication for use	For the in vitro diagnostic use in the quantitative determination of total 25 (OH) vitamin D in human serum and plasma (EDTA, lithium-heparin, sodium-heparin) using the ADVIA Centaur XP system. The ADVIA Centaur VitD assay is intended as an aid in the determination of vitamin D sufficiency.	Similar The IDS 25-OH Vitamin D EIA kit is an enzymeimmunoassay intended for the quantitative determination of 25-Hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. Results are to be used in conjunction with other clinical and laboratory data to assist the clinician in the assessment of vitamin D sufficiency in adult populations.
Sample Type	Serum and Plasma	same
Reagent storage temperature	2-8°C	same
Interpretation of results	Standard curve	same
Expected Values	Deficiency < 10 ng/mL Insufficiency 10-29 ng/mL Sufficiency 30-100 ng/mL Toxicity > 100ng/mL Ranges established for apparently healthy adults not on supplements: 10.6 ng/mL to 43.4 ng/mL n = 542	Same Ranges established adults 19.1 ng/mL to 57.6 ng/mL n = 36

Assay Differences

Items	ADVIA Centaur Vitamin D Total assay	IDS 25-OH Vitamin D EIA assay (Predicate Device) k021163
	Differences	
Platform	ADVIA Centaur XP	ELISA plate read on a plate reader
Assay principle	Chemiluminescence	ELISA
Assay procedure	Automated	Manual
Approximate Assay time	18 minute	3.5 hours
Assay Range	4.2 to 150 ng/mL	5.9 to 120 ng/mL
Traceability	Traceable to LC-MS/MS	Standardized using UV quantification of 25-(OH) vitamin D

Calibrator Similarities

Items	ADVIA Centaur Vitamin D Total assay calibrators	IDS 25-OH Vitamin D EIA assay calibrators (Predicate Device) k021163
Similarity		
Intended Use/Indication for use	For *in vitro* diagnostic use in calibrating ADVIA Centaur® systems Vitamin D Total (VitD) assay.	Similar
Antigen used in calibrators	25-(OH) vitamin D_3	same
Storage temperature	2-8°C	same.

Calibrator Differences

Items	ADVIA Centaur Vitamin D Total assay	IDS 25-OH Vitamin D EIA assay calibrators (Predicate Device) k021163
Differences		
Number of calibrators	2	6
Matrix	Lyophilized human plasma	Lyophilized human serum

QC Similarities

Items	ADVIA Centaur Vitamin D Total assay controls	IDS 25-OH Vitamin D EIA assay controls (Predicate Device) k021163
Similarity		
Intended Use/Indication for use	For *in vitro* diagnostic use to monitor the precision and accuracy of the ADVIA Centaur® VitD assay on the ADVIA Centaur systems.	Similar
Antigen used in controls	25-(OH) vitamin D_3	same
Number of Levels	2	same
Storage temperature	2-8°C	same

QC Differences

Items	ADVIA Centaur Vitamin D Total assay controls	IDS 25-OH Vitamin D EIA assay controls (Predicate Device) k021163
Differences		
Matrix	Lyophilized human plasma	Lyophilized human serum

MCM Similarities

Items	ADVIA Centaur Vitamin D Total assay MCMs	Maine Standards Company VALIDATE Thyroid Calibration Verification Test Set (K062501)
Similarity		
Intended Use/Indication for use	The ADVIA Centaur® Vitamin D Total (VitD) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur VitD assay.	The VALIDATE Thyroid Calibration Verification Test Set solutions are for *in vitro* diagnostic use in the uantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual chemistry systems.
Number of Levels	5	Same

MCM Differences

Items	ADVIA Centaur Vitamin D Total assay MCMs	Maine Standards Company VALIDATE Thyroid Calibration Verification Test Set (K062501)
Differences		
Matrix	Human plasma	Human Serum
Form	Lyophilized	liquid
Analyte	25 (OH) vitamin D	Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol.

Performance:

Substantial equivalence for the ADVIA Centaur Vitamin D Total assay was demonstrated by testing several method performance characteristics including Analytical Sensitivity, linearity, imprecision, method comparison, interfering substances, and specificity. The following tables summarize the analytical sensitivity, linearity, precision (total), interfering substances, specificity, serum / plasma equivalency and method comparison results.

All of the evaluation studies gave acceptable results compared to the predicate device. These studies support that the ADVIA Centaur Vitamin D Total assay (including the

calibrators and controls) are substantially equivalent to the IDS 25-Hydroxy Vitamin D EIA that is currently marketed.

Analytical Sensitivity

LoB = 1.60 ng/mL
LoD = 3.2 ng/mL
LoQ = 4.2 ng/mL

Imprecision

ADVIA Centaur Vitamin D Total Assay		IDS 25-Hydroxy Vitamin D EIA	
Level (ng/mL)	Total CV (%) n = 160	Level (ng/mL)	Inter assay CV (%) n = 11
11.7	11.1		
18.0	9.6		
32.4	9.8	40.3	4.6
49.9	8.2		
55.8	7.8	72.0	6.4
132.1	4.8	132.0	8.7

Specificity

The ADVIA Centaur VitD Total assay shows high specificity for 25(OH) vitamin D2 and 25(OH) vitamin D_3. The following compounds were tested with total 25(OH) vitamin D concentrations of 35 and 115 ng/mL. Percent change is calculated as:
Percent cross-reactivity = (corrected assay value / amount of compound spiked) x 100

Compound	Concentration (ng/mL)	Cross-Reactivity (%)
1, 25 $(OH)_2$ Vitamin D_2	100	4.0
1, 25 $(OH)_2$ Vitamin D_3	100	1.0
25 OH Vitamin D_2	30	104.5
25 OH Vitamin D_3	30	100.7
Paricalcitol	24	0.1
3-epi-25-OH Vitamin D_3	100	1.1
Vitamin D_2	1000	0.5
Vitamin D_3	1000	0.3

Interfering Substances

Interfering substances were tested as described in CLSI Document EP7-A2 using the ADVIA Centaur VitD assay.

Specimens That Are	Demonstrate ≤ 10% Change in Results Up To
hemolyzed	155 mg/dL of hemoglobin
lipemic	540 mg/dL of triglycerides
icteric	40 mg/dL of conjugated bilirubin
icteric	40 mg/dL of unconjugated bilirubin

Specimens That Contain	Demonstrate ≤ 10% Change in Results Up To
cholesterol	350 mg/dL
uric acid	20 mg/dL
human immunoglobulin	12 g/dL

Correlation

(y =ADVIA Centaur Vitamin D assay vs. x = IDS 25-OH Vitamin D EIA assay comparison method/system)

IDS vs Centaur					
X Axis	Y Axis	n	r	Slope	Y-int
IDS	Centaur VitD	195	.960	1.0	+2.22

Serum / Plasma (lithium heparin and EDTA)

The ADVIA Centaur VITD assay was evaluated using different sample matrices and tube collection types. A matrix study was performed using matched specimens drawn in different tube types,including serum red top, SST, EDTA, lithium heparin, and sodium heparin. Vitamin D values ranged from 11.9 to 136.9 ng/mL (29.8 to 342.3 nmol/L). Linear regression analysis was performed using the following:

- serum (x) vs. SST (y1)
- serum (x) vs. EDTA (y2)
- serum (x) vs. lithium heparin (y3)
- serum (x) vs. sodium heparin (y4)

No significant differences between tube types was observed. The following results were obtained:

Tube Types	N	Range (ng/mL)	Slope	Intercept	R
Serum vs. SST	231	11.9 – 136.9	1.01	-0.33	0.994
Serum vs. EDTA	231	11.9 – 136.9	1.09	-0.17	0.993
Serum vs. Lithium Heparin	231	11.9 – 136.9	1.04	0.18	0.992
Serum vs. Sodium Heparin	231	11.9 – 136.9	1.04	0.90	0.992

Conclusions:

The Siemens Healthcare Diagnostics ADVIA Centaur Vitamin D Total assay (including calibrators and controls) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed IDS 25-Hydroxy Vitamin D EIA (K021163).

The Siemens Healthcare Diagnostics ADVIA Centaur Vitamin D Total assay MCMs are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed VALIDATE Thyroid Calibration Verification Test Set (K062501).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Mr. Neil Parker
511 Benedict Avenue
Tarrytown, New York 10509

OCT 14 2011

Re: k110586
Trade Name: ADVIA Centaur Vitamin D Total (VitD) Assay
ADVIA Centaur Vitamin D Total (VitD) Calibrators
ADVIA Centaur Vitamin D Total (VitD) QC
ADVIA Centaur Vitamin D Total (VitD) Master Curve Material
Regulation Number: 21 CFR §862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Codes: MRG, JIS, JJX
Dated: September 15, 2011
Received: September 16, 2011

Dear Dr. Neil Parker,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food; Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110586
Device Name: ADVIA Centaur Vitamin D Total Assay
Indication for Use:

The ADVIA Centaur Vitamin D Total (VitD) assay is for in vitro diagnostic use in the quantitative determination of total 25 (OH) vitamin D in human serum and plasma (EDTA, lithium-heparin, sodium-heparin) using the ADVIA Centaur XP system. The ADVIA Centaur VitD assay is intended as an aid in the determination of vitamin D sufficiency.

The ADVIA Centaur Vitamin D Total (VitD) Calibrators is for *in vitro* diagnostic use in calibrating ADVIA Centaur® systems Vitamin D Total (VitD) assay.

The ADVIA Centaur Vitamin D Total (VitD) QC is for *in vitro* diagnostic use to monitor the precision and accuracy of the ADVIA Centaur® VitD assay on the ADVIA Centaur systems.

The ADVIA Centaur® Vitamin D Total (VitD) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur VitD assay.

Prescription Use X And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) K110586