

K112725

JAN 20 2012

510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: LIAISON® 25 OH Vitamin D TOTAL Assay
Common Names/Descriptions: Vitamin D Reagents
Classification Names: Vitamin D Test System
Classification Number: 862.1825
Product Code: MRG

PREDICATE DEVICE:

LIAISON® 25 OH Vitamin D TOTAL Assay
(K071480)

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum to be used in the assessment of vitamin D sufficiency using the LIAISON® Analyzer family. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.

KIT DESCRIPTION:

The LIAISON® 25 OH Vitamin D assay is a direct competitive chemiluminescence immunoassay (CLIA) for quantitative determination of total 25 OH vitamin D in serum. During the first incubation, 25 OH Vitamin D is dissociated from its binding protein and binds to the specific antibody on the solid phase. After 10 minutes the tracer, (vitamin D linked to an isoluminol derivative) is added. After a second 10 minute incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added to initiate a flash chemiluminescent reaction. The light signal is measured by a

photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of 25 OH vitamin D present in calibrators, controls, or samples.

Changes were made to the assay's magnetic particle surface and the Assay Buffer formulation to reduce reaction with rare heterophilic antibodies.

PERFORMANCE DATA:

Method Comparison:

A method comparison study was performed following CLSI EP9-A2. In the study, samples were obtained from a clinical reference laboratory. A total of 587 samples were tested by LIAISON® 25 OH Vitamin D TOTAL and by DiaSorin 25 OH Vitamin D RIA. Linear regression analyses were performed on the results across the measuring range of the LIAISON® assay. The resulting regression equation was: $LIAISON^{\circledR} = 1.047 (RIA) + 2.41$; $R = 0.936$.

Reproducibility/Precision:

A 20 day reproducibility/precision study was performed at DiaSorin Inc. and 2 external sites. A coded panel comprised of 6 serum samples was prepared by DiaSorin Inc. The LIAISON® 25 OH Vitamin D TOTAL controls (2 levels) were also tested in the study. The CLSI document EP15-A2 was consulted in the preparation of the testing protocol.

The 20 day results for the 3 sites are summarized in the following table.

Sample ID	Mean (ng/mL)	Intra-Run		Total	
		SD	%CV	SD	%CV
Sample #5	7.9	0.6	7.7%	1.0	12.6%
Sample #1	12.0	0.7	5.8%	1.3	11.1%
Kit Control 1	18.0	0.9	5.0%	1.7	9.7%
Sample #2	20.4	1.0	5.0%	2.1	10.4%
Sample #3	24.3	1.2	5.0%	2.6	10.6%
Sample #4	56.8	2.9	5.0%	5.8	10.3%
Kit Control 2	61.8	3.0	4.9%	5.8	9.5%
Sample #6	112.1	5.4	4.8%	12.2	10.8%

Dilution Linearity:

Two (2) serum pools were diluted and analyzed with 1 LIAISON® 25 OH Vitamin D TOTAL Assay kit lots following CLSI EP6-A. The results for each sample were analyzed by a linear regression of observed Vitamin D concentration versus expected Vitamin D concentration. The resulting regression equation is: $Observed = Expected \ 1.01x - 0.180$; $R = 0.995$.

Functional Sensitivity

The functional sensitivity is defined as the dose concentration at which the %CV exceeds 20%, was evaluated according to CLSI EP17-A. Samples were prepared at

nominal concentrations of 2.0 – 14.0 ng/mL and assayed in multiple runs to determine mean concentration and %CV. Sample concentration was plotted against %CV and a regression was prepared to determine the functional sensitivity. The derived functional sensitivity from the regression equation is ≤ 4.0 ng/mL.

Interfering Substances

Interfering substances were tested in the LIAISON® 25 OH Vitamin D Assay. The results are presented in below.

Specimens That Are	Demonstrate $\leq 10\%$ change in Results Up To
Hemolyzed	200 mg/dL of hemoglobin
Lipemic	589 mg/dL of triglycerides
Icteric	40 mg/dL of conjugated bilirubin
Icteric	40 mg/dL of unconjugated bilirubin
Specimens That Contain	Demonstrate $\leq 10\%$ change in Results Up To
Cholesterol	301 mg/dL
Uric acid	20 mg/dL
Total Protein	12 g/dL

CONCLUSION:

The material submitted in this premarket notification is complete and supports the basis for substantial equivalence. The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.



DiaSorin Inc
c/o Judi Smith LLC
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10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 20 2012

Re: k112725
Trade Name: LIAISON® 25 OH Vitamin D TOTAL Assay
Regulation Number: 21 CFR §862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Codes: MRG
Dated: December 20, 2011
Received: December 22, 2011

Dear Ms. Smith:

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 Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5 INDICATION FOR USE

510(k) Number (if known):

Device Name: LIAISON® 25 OH Vitamin D TOTAL Assay

Indication For Use:

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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) 112725