JAN 2 5 2013

5.0 510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	LIAISON® Testosterone LIAISON® Testosterone Control Set
Common Names/Descriptions:	Testosterone Assay
Classification:	Class I, reserved, 21 CFR 862.1680, Testosterone Test System, Clinical Chemistry (75) Class I, reserved, 21 CFR 862.1660, Quality Control Material, Clinical Chemistry (75)
Product Code:	CDZ, JJX

PREDICATE DEVICE:

Roche Cobas® Testosterone II Test
Reference K093421
Roche Elecsys® PreciControl Universal
Reference K090541

DEVICE DESCRIPTION:

INTENDED USE:

The DiaSorin LIAISON® Testosterone is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and plasma on the LIAISON® Analyzer. The assay is intended for *in vitro* diagnostic use.

Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in male subjects and, in female subjects hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The DiaSorin LIAISON® Testosterone Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® Testosterone immunoassay.

KIT DESCRIPTION:

The LIAISON® Testosterone assay's method for quantitative determination of testosterone is a direct, competitive, chemiluminescence immunoassay (CLIA). Specific antibody to testosterone is bound to magnetic particles (solid phase) and testosterone is linked to an isoluminol derivative. During the incubation, testosterone is dissociated from its binding protein and competes with labeled testosterone for binding sites on the antibody. After the incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of testosterone present in calibrators, controls, or samples. All assay steps and incubations are performed by the LIAISON® Analyzer.

Two point kit calibrators are used to establish specific working curves based on assay master curves stored on the Analyzer.

The LIAISON® Testosterone reagent kit consists of a reagent intrgral which contains antibody coated magnetic particles (2.3 mL), conjugate (12 mL) and assay buffer (12 mL) reagents. Two levels of ready to use calibrators (2 vials each level, 2.0 mL per vial) are provided with each kit. Each kit consists of 100 tests.

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® Testosterone is substantially equivalent in principle and performance to the Roche Cobas® Testosterone II Test (K093421) which was FDA cleared 4/28/2010.

DiaSorin LIAISON® Testosterone Similarities and Differences

Characteristic	LIAISON® Testosterone	Roche Cobas® Testosterone II (K093421)
Intended Use	Intended for the in vitro quantitative determination of testosterone in human serum and EDTA plasma.	Intended for the in vitro quantitative determination of testosterone in human serum and plasma.
Indications for Use	Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to	Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to

	tumors, polycystic ovaries, and adrenogenital syndromes.	tumors, polycystic ovaries, and androgenital syndromes.
Assay Type	Chemiluminescent Immunoassay	Electrochemiluminescence Immunoassay "ECLIA"
Analyte	Testosterone	Testosterone
Calibration	Two-point verification of stored master curve.	Same
Sample Handling	Automated	Same
Unit of Measure	ng/mL,ng/dL or nmol/L	Same
Controls	2 levels	2 levels
Measurement System	Photomultiplier (flash chemiluminescence reader)	Photomultiplier (flash chemiluminescence reader)
Calibrators	Included with kit	Provided separately
Capture Antibody	Mouse monoclonal antibodies to testosterone	Biotinylated sheep monoclonal antibodies to testosterone
Measuring range	16.0 – 1500 ng/dL	2.5 – 1500 ng/dL
Sample size	100 uL	20 uL
Sample matrix	Serum and EDTA plasma	Serum and plasma (Li-heparin, K_2-EDTA, and K_3 EDTA
Reagent Storage	In refrigerator @ 2-8° C.	On analyzer or in refrigerator @ 2-8°C.
Open Storage @ 2-8° C	4 weeks	12 weeks
Open Storage on analyzer	NA	8 weeks

DiaSorin LIAISON® Testosterone Control Set Similarities and Differences

Characteristic	LIAISON® Testosterone Control Set	Roche PreciControl Universal 1 and 2 (K090541)
Intended Use	Intended for use as assay quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® Testosterone immunoassay.	Intended for use as quality control of Elecsys® immunoassays on the Elecsys® and Cobas® immunoassay analyzers®
Matrix	Human serum	Same
Levels	Two concentrations : low and high	Same
Reagent Format	Liquid 2 vials x 3.5 mL each level	Lyophilized 2 vials x 3.0 ml each level
Handling	Ready to use	Reconstitute with distilled water and allow 30 minutes for reconstitution.
Storage @ 2-8° C	Unopened store at 2-8° C until expiration date	Same

Open Storage	4 weeks at 2-8° C.	Reconstituted : On analyzer at 20-25° C up to 5 hrs ; At 2-8° C for 3 days ; at -20° C for up to 1 month

PERFORMANCE DATA:

Method Comparison:

The method comparison included one hundred eighty four (184) serum samples that spanned the reportable range of each assay (n = 184). Samples were tested by the DiaSorin LIAISON® Testosterone assay (expressed as ng/dL) and the predicate device Roche Cobas® Testosterone II Test (K093421) on the Elecsys analyzer (expressed as ng/dL). The method comparison study was performed according to CLSI EP9-A2 guidelines.

One hundred sixty two (162) of the 184 serum samples tested were analyzed. One sample read above the upper limit of the reportable range and 21 samples read below the measuring range of the LIAISON® Testosterone assay and therefore, were not included in the analysis. Individual testosterone results were plotted.
Passing & Bablok linear regression analysis was performed on the results across the measuring range of LIAISON® Testosterone assay yielding agreement of y = 0.9458x - 0.1002, R = 0.990. The 95% confidence interval for the slope was 0.92 to 0.96, and the 95% confidence interval for the intercept was -1.88 to 1.80 ng/dL.

LoB/LoD/LoQ

The Limit of Blank, Limit of Detection, and Limit of Quantitation were determined according to CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation.
The following limits were determined with the LIAISON® Testosterone assay:

Limit of Blank: ≤ 3.1 ng/dL
Limit of Detection: 9.8 ng/dL
Limit of Quantitation: 16.0 ng/dL

Reference Range/Expected Values:

The reference range study was performed according to CLSI Approved Guideline C28-A3. Human serum samples from apparently healthy adults were tested to determine the reference range for the LIAISON® Testosterone assay into the follwoing gender and age groups.

Population	N	Median Testosterone Conc. ng/mL (ng/dL)	Central 95% Interval ng/mL (ng/dL)
Males 18-49 years	161	4.39 (439)	1.20 - 10.19 (120 – 1019)
Males ≥ 50 years	132	4.53 (453)	1.95 - 8.95 (195 – 895)
Females 18-49 years	202	0.24 (24.0)	< 0.16 - 0.73 (<16.0 – 73.0)
Females ≥ 50 years	127	0.22 (22.0)	< 0.16 - 0.51 (<16.0 – 51.0)

Reproducibility/Precision:
A twenty day reproducibility/precision study was performed at DiaSorin Inc. and 2 external sites. A coded panel comprised of 6 frozen serum samples was prepared by DiaSorin. The coded panel contained 2 of each of low, medium and high level samples which spanned the measuring range of the assay. The LIAISON® Testosterone Controls (2 levels) were also tested in the study. The CLSI document EP5-A2 was consulted in the preparation of the testing protocol.

Results:
The twenty day results for all three sites are summarized in Table 1 as sample overall mean testosterone concentration in ng/dL, computed SDs and %CVs for within run and total across lots and across sites.

Table 1: Reproducibility/Precision Results – 20 day Combined 3 Sites

Sample ID	N	Mean (ng/dL)	Within Run		Total Across Lots / Across Sites	
			SD	%CV	SD	%CV
Level 1	480	219	8.0	3.4%	2.0	9.1%
Level 2	480	781	22.0	2.8%	55.0	7.1%
POOL 1	480	37.0	3.0	7.3%	5.0	14.0%
POOL 2	480	83.0	5.0	5.5%	9.0	10.5%
POOL 3	480	237	11.0	4.5%	20.0	8.6%
POOL 4	480	418	18.0	4.3%	38.0	9.2%
POOL 5	480	1048	37.0	3.5%	94.0	9.0%
POOL 6	480	1325	42.0	3.2%	105	7.9%

Dilution Linearity:
Three (3) samples of each sample type, serum, SST serum, and EDTA plasma were diluted with calibrator matrix or a low human serum or plasma sample to yield sample concentrations that spanned the measuring range (16.0 – 1500 ng/dL) and analyzed by the LIAISON® Testosterone following CLSI EP6-A.

The mean results for each sample type were analyzed by a linear regression of Observed Testosterone Concentration versus Expected Testosterone Concentration in ng/dL with the following resulting equations:

Serum: $y = 1.0269x - 0.6135$, $R^2 = 0.9862$
SST Serum: $y = 1.0096x - 0.3.297$, $R^2 = 0.9907$
EDTA plasma: $y = 0.9986x + 15.91$, $R^2 = 0.9847$

Specificity
The cross-reactivity of the LIAISON® Testosterone assay was evaluated by adding the following substances to serum pools containing testosterone at 2 concentrations. The

samples were analyzed and the percent (%) cross-reactivity calculated using the following formula:

% Cross-reactivity = (Corrected Assay value/Concentration Spiked)*100

The observed cross-reactivities are listed below:

Cross reactant	Spiked Concentration ng/mL	% Cross reactivity
Androstenedione	100	≤ 4.27
Cortisol	1000	≤ 0.03
Cortisone	2000	≤ 0.01
Danazol	1000	≤0.02
Dexamethasone	2000	≤ 0.01
DHEA	1000	≤ 0.02
DHEA-S	50000	≤ 0.01
D-5-Androstene-3B-17B-diol	1000	≤ 0.06
Estrone	1000	≤ 0.03
Ethisterone	1000	≤ 0.43
Nandrolone	100	≤ 3.33
Norgesterel	1000	≤ 0.02
Testosterone propionate	50	≤ 7.48
5-a-Androstane-3B,17B-diol	500	≤ 0.81
5-a-Dihydrotestosterone	500	≤ 2.37
11-B-Hydroxytestosterone	50	≤ 15.28
11-Keto-testosterone	10	≤ 37.70
Prednisone	1000	≤ 0.03
Prednisolone	1000	≤ 0.04
Progesterone	1000	≤ 0.12
17-a-Estradiol	1000	≤ 0.02

Interfering Substances

Controlled studies of potentially interfering substances at two testosterone levels showed no interference at the concentration for each substance listed below in the LIAISON® Testosterone assay. The testing was based on CLSI-EP07-A2.

Substance	Tested Concentration
Hemoglobin	600 mg/dL
Bilirubin (unconj)	20 mg/dL
Triglycerides	1000 mg/dL
Cholesterol	500 mg/dL
HAMA	Up to 1753 ng/mL

CONCLUSION:

The material submitted in this premarket notification is complete and supports the basis for substantial equivalence to the Roche Cobas® Testosterone II Test (K093421).
The labelling is sufficient and satisfies the requirements of 21 CFR 809.10.

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

January 25, 2013

Diasorin, Inc.
c/o Mr. John Eskdale
1951 Northwestern Ave.
Stillwater, MN 55082

Re: k122793
Trade/Device Name: LIAISON Testosterone
LIAISON Testosterone Control Set
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Code: CDZ, JJX
Dated: December 14, 2012
Received: December 17, 2012

Dear Mr. Eskdale:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122793

Device Name: LIAISON® Testosterone and LIAISON® Testosterone Control Set

Indications for Use:

The DiaSorin **LIAISON® Testosterone** assay is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and plasma on the LIAISON®Analyzer. The assay is intended for *in vitro* diagnostic use.

Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in male subjects and, in female subjects hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The DiaSorin **LIAISON® Testosterone Control Set** is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® Testosterone immunoassay.

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 Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)__k122793__