October 15, 2020

DiaSorin Inc.
Mari Meyer
Vice President, Regulatory and Clinical Affairs, North America
1951 Northwestern Avenue
Stillwater, MN 55082

Re: K201908
Trade/Device Name: LIAISON® Testosterone xt
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone Test System
Regulatory Class: Class I, reserved
Product Code: CDZ
Dated: September 15, 2020
Received: September 18, 2020

Dear Mari Meyer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201908

Device Name
LIAISON® Testosterone xt

Indications for Use *(Describe)*
The LIAISON® Testosterone xt is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL 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 males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The test has to be performed on the LIAISON® XL Analyzer.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 6.0 510(k) SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

6.1. SUBMITTER INFORMAITON

Submitter:	DiaSorin Inc. 1951 Northwestern Avenue P.O. Box 285 Stillwater, MN 55082-0285
Contact:	Mari Meyer Vice President, Regulatory and Clinical Affairs Email: mari.meyer@diasorin.com Phone: (715) 410-7149 Fax: (651) 351-5669
Date Summary Prepared:	July 02, 2020

6.2. DEVICE INFORMATION

Proprietary Name:	LIAISON® Testosterone xt (k201908)
Common Name:	Testosterone test system
Predicate Device:	LIAISON® Testosterone (k122793)

6.3. REGULATORY INFORMATION

Proprietary Name	Classification Name	Regulation Section	Product Code	Device Class	Classification Panel
LIAISON® Testosterone xt (k201908)	Radioimmunoassay, Testosterones And Dihydrotestosterone	862.1680	CDZ	Class I, Reserved	Clinical Chemistry (75)

6.4. DEVICE DESCRIPTION

PRINCIPLE OF PROCEDURE
The fundamental scientific technology (Principle of the Test) of the device as described in its current labeling has not changed as a result of the modifications.

The LIAISON® Testosterone xt 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.

DEVICE CONTENT
The raw materials, formulation, and manufacturing procedures of the assay components have not changed as a result of the modifications.

Reagent Integral
The LIAISON® Testosterone xt is an *in vitro* diagnostic device consisting of reagents provided in individual compartments within a plastic container called the Reagent Integral. The components provided in the unitized Reagent Integral include: PMP (paramagnetic particles), conjugate and assay buffer. All reagents in the integral are supplied ready to use. The assay configuration for the LIAISON® Testosterone xt allows for the performance of 100 tests.

Additional Components Not on the Reagent Integral
The two-point calibrators are provided in the same kit box, but separate from the Reagent Integral. The two-point calibrators are supplied ready to use.

Materials Required but Not Provided
The LIAISON® Testosterone xt assay is performed on the LIAISON® XL Analyzer (Model I0050; originally FDA cleared under k103529), a fully automated system with continuous loading combining the chemiluminescence technology with magnetic microparticles as the solid phase. Other accessories/consumables such as the LIAISON® XL Cuvettes, LIAISON® XL Starter Kit, LIAISON® Wash/System Liquid, LIAISON® XL Waste Bags, and the LIAISON® XL Disposable Tips are supplied separately.

6.5. INTENDED USE /INDICATIONS FOR USE

The Intended Use/Indications for Use of the device as described in its current labeling has not changed as a result of the modifications.

The LIAISON® Testosterone xt is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL 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 males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The test has to be performed on the LIAISON® XL Analyzer.

6.6. REASON FOR SUBMISSION

This Special 510(k) is being filed to seek FDA clearance for the LIAISON® Testosterone xt assay, a modified version of the existing LIAISON® Testosterone assay, which is currently cleared (k122793, FDA cleared on January 25, 2013).

6.7. DESCRIPTION OF DEVICE MODIFICATION

The LIAISON® Testosterone device is being modified to extend the assay measuring range, calibration curve stability, and open use stability for the reagent integral and calibrators. Additionally, the modified device has a new proprietary name, part number, and is performed on the LIAISON® XL Analyzer. The modifications do not change the Intended Use/Indications for Use, the fundamental scientific technology, reagent formulation, assay configuration, manufacturing procedures, principle of operation, or safety and effectiveness of the device.

A summary of the modifications and the rationale for the changes between the current cleared device, LIAISON® Testosterone (k122793) and the LIAISON® Testosterone xt (modified device) are provided in Table 6-1.

Table 6-1: Summary of the Modifications

Modification to the LIAISON® Testosterone		
Cleared Device (k122793)	**Modification**	**Rationale**
Name/Part Number		
LIAISON® Testosterone 310410	LIAISON® Testosterone xt 318410	**N/A**
Assay Measuring Range		
0.16 – 15.0 ng/mL	Extend Assay Measuring Range: 0.024 – 15.0 ng/mL	The extended Assay Measuring Range and increased sensitivity is needed to satisfy current market needs.
Reagent Integral Storage and Stability		
After opening and each use, the Reagent Integral should be sealed with the tape provided with the kit, placed in the kit box and returned to storage at 2-8°C. Undue exposure to light should be avoided. Open use is four weeks when properly stored.	Extend Open Use Stability of Reagent Integral up to **eight (8) weeks** after opening when properly stored.	The extended Open Use Stability of the Reagent Integral once opened is desired to satisfy all customer needs: - small labs, with a low ratio of test per month; - large labs with high number of tests per months.
Calibrator Storage and Stability		
LIAISON® Testosterone calibrators are liquid and ready to use. After use, the calibrators should be re-capped, and returned to storage at 2-8°C. Open use is 4 weeks when properly stored.	Extend Open Use Stability of Calibrators up to **eight (8) weeks** after opening when properly stored.	The extended stability of the Calibrators once opened is desired to satisfy all customer needs: - small labs, with a low ratio of test per month; - large labs with high number of tests per months.
Calibration Curve Stability		
Recalibration in triplicate is mandatory whenever at least one of the following conditions occurs: - The previous calibration	Extend Calibration Curve Stability up to **four (4) weeks.**	The extended calibration stability is desired to satisfy all customer needs: - small labs, with a low ratio of test per month;

was performed more than 7 days before.		- large labs with high number of tests per months.

6.8. COMPARISON TO PREDICATE DEVICE

The following table (Table 6-2) provides a summary of the similarities and differences between the predicate device, the LIAISON® Testosterone (k122793), and the modified device (k201908).

Table 6-2: Comparison to Predicate Device

Characteristic	Predicate Device **LIAISON® Testosterone (k122793, cleared 01/25/2013)**	Modified Device **LIAISON® Testosterone xt (k201908)**
SIMILARITIES		
Intended Use/Indications for Use	The LIAISON® Testosterone is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA 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 males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes. The test has to be performed on the LIAISON® Analyzer Family*. *(LIAISON® and LIAISON® XL)	The LIAISON® Testosterone xt is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL 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 males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes. The test has to be performed on the LIAISON® XL Analyzer.
Principle of the Procedure	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	Same

	proportional to the concentration of testosterone present in calibrators, controls, or samples.	
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	Same
Sample Handling/Assay Processing	Automated	Same
Reagent Integral Configuration/ Formulation (1 compartment each reagent)	• Magnetic Particles: Magnetic particles coated with mouse MAb against testosterone, phosphate buffer, BSA, goat immunoglobulin, and 0.2% Proclin® 300. • Conjugate: Testosterone conjugated to an isoluminol derivative, in phosphate buffer with surfactant, BSA and <0.1% Sodium Azide. • Assay Buffer: Phosphate buffer with surfactant, BSA, and <0.1% Sodium Azide.	Same
Reagent Volume Provided	• Magnetic particles: 1 compartment (2.4 mL) • Conjugate: 1 compartment (12 mL) • Assay Buffer: 1 compartment (12 mL)	Same
Tests per Kit	100 tests	Same
Raw materials	• Antigen: Testosterone • Detector: Testosterone conjugated to an isoluminol derivative. • Capture: Magnetic particles coated with mouse MAb against testosterone.	Same
Calibrator 1	Calibrator 1, low: containing hormone free human serum spiked with testosterone, 0.2% Proclin® 300.	Same
Calibrator 2	Calibrator 2, high: containing hormone free human serum spiked with testosterone, 0.2% Proclin® 300.	Same
Calibrator Configuration	2 vials each level 2.0 mL/vial, ready to use.	Same
Storage of Unopened Reagents	Store at 2-8° C until ready to use	Same
Shelf Life	12 months	Same
Measured Analyte	Testosterone	Same
Sample Type	Human Serum and EDTA plasma	Same
Sample Volume	100 uL	Same
Sample Storage	If the assay is performed within 5 days of sample collection, the samples should be kept at 2-8°C; otherwise they should be stored frozen (-20°C or below).	Same

Assay Procedure	1. Dispense sample, calibrator or control into reaction module. 2. Dispense magnetic particle and assay buffer into reaction module. 3. Incubate 4. Dispense conjugate into reaction module. 5. Incubate 6. Wash with Wash/System liquid 7. Add the Starter Reagents and measure the light emitted.	Same
Total Incubation	13 minutes	Same
Measurement System	Photomultiplier (flash chemiluminescence reader)	Same
Calibration	Two point verification of stored master curve	Same
Unit of Measure	ng/mL (ng/dL)	Same
Calibrators	Included with kit	Same
Controls	Provided Separately	Same
DIFFERENCES		
Proprietary	LIAISON® Testosterone	LIAISON® Testosterone xt
Product Code	310410	318410
Instrument Platform(s)	LIAISON® and LIAISON® XL Analyzer	LIAISON® XL Analyzer
Assay Measuring	0.16 to 15.0 ng/mL	0.024 to 15.0 ng/mL
Limit of Blank (LoB)	≤ 0.031 ng/mL	≤ 0.005 ng/mL
Limit of Detection (LoD)	0.098 ng/mL	0.010 ng/mL
Limit of Quantitation (LoQ)	0.160 ng/mL	0.024 ng/mL
Method Comparison	A Passing and Bablok regression analysis yeilded an agreement of y = 0.9390x – 0.1002 for the LIAISON® Testosterone assay versus a commercially available immunoassay. The 95% confidence intervals for the slope are 0.92 to 0.96 and -1.88 to 1.80 ng/dL for the intercept.	A Passing-Bablok regression analysis yielded agreement of y = 0.99x – 1.77 ng/dL for the LIAISON® Testosterone xt versus the CDC HoSt Testosterone RMP ID-LC-MS/MS values. The 95% confidence intervals for the slope are 0.97 to 1.02 and -3.22 to -0.35 ng/dL for the intercept.
Precision	Total/Across Lots (%CV): 7.9% – 14.0%	Total/Across Lots (%CV): 3.5% – 7.9 %
Linearity	The resulting equations for each sample type are: • Serum: Observed Analyte = 0.9942x – 16.062; R^2 = 0.9959 • SST Serum: Observed Analyte = 1.0188x – 14.531; R^2 = 0.9965 • EDTA plasma: Observed Analyte = 1.0057x – 13.029; R^2 = 0.9913	The resulting equations for each sample type are: • Serum: Observed Analyte = 0.995x + 0.0346; R^2 = 0.9928 • SST Serum: Observed Analyte = 1.0225x – 57.853; R^2 = 0.9914 • EDTA plasma: Observed Analyte = 1.0337x – 31.889; R^2 = 0.9955

Recovery	Mean Recovery (%): 97% Range (%): 91% - 105%	Mean Recovery (%): 99% Range (%): 93% - 105%
Open Use Stability: Reagent	Open use is four weeks when properly stored.	Open use is 8 weeks when properly stored.
Open Use Stability: Calibrators	Open use is 4 weeks when properly stored.	Open use is 8 weeks when stored at 2-8°C.
Calibration Curve Stability	7 days	28 days

6.9. RISK MANAGEMENT

The Risk Management was performed in compliance with EN ISO 14971:2012 *Medical Devices – Application of Risk Management to Medical Devices*. The Failure Modes Effects Analysis (FMEA) methodology was used to systematically identify, estimate, evaluate, control and report risks to ensure the development and maintenance of a safe and effective product that meets its intended use.

6.10. VERIFICATION AND VALIDATION SUMMARY

All verification and validation activities were performed in accordance to relevant standards, established plans, protocols, and Design Control procedures. Testing verified all acceptance criteria were met. Verification of the changes did not raise any new items of safety and effectiveness.

6.11. SUMMARY OF PERFORMANCE DATA

Refer to Table 6-2: Comparison to Predicate Device for the summary results of the verification and validation testing.

6.12. SUBSTANTIAL EQUIVALENCE STATEMENT

All verification and validation testing conducted with the LIAISON® Testosterone xt assay demonstrate that the modified device met the predetermined acceptance criteria, supporting the determination of substantial equivalence to the predicate device.

The modifications to the predicate device to provide improved sensitivity and stability do not substantially change the device. The validation and verification data demonstrate that the performance of the LIAISON® Testosterone xt to detect testosterone is substantially equivalent to the predicate device.

6.13. CONCLUSION

The material submitted in this Special 510(k): Device Modifications of the LIAISON® Testosterone (k122793) is complete and supports a substantial equivalence decision. The labeling satisfies the requirements of 21 CFR 809.10.