February 9, 2021

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

Re: K210272
Trade/Device Name: LIAISON Anti-HAV
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Assays
Regulatory Class: Class II
Product Code: LOL, JJF
Dated: January 25, 2021
Received: February 1, 2021

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,

Maria Garcia, Ph.D.
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210272

Device Name
LIAISON® Anti-HAV

Indications for Use *(Describe)*
The LIAISON® Anti-HAV assay is an in vitro chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

This assay is not intended for screening blood or solid or soft tissue donors.

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:	January 25, 2021

6.2. DEVICE INFORMATION

Proprietary Name:	Liaison® Anti-HAV
Common Name:	Hepatitis Anti-HAV, serological assay; Automated Chemiluminescent Immunoassay Analyzer
Predicate Device:	Liaison® Anti-HAV (K193532)

6.3. REGULATORY INFORMATION

Proprietary Name	Classification Name	Regulation Section	Product Code	Device Class	Classification Panel
LIAISON® Anti-HAV	Hepatitis A Test (antibody And Igm Antibody);	21 CFR 866.3310	LOL	Class II	Microbiology
LIAISON® XS	Analyzer, Chemistry, Micro, For Clinical Use	21 CFR 862.2170 -	JJF	Class I	Microbiology, Clinical Chemistry

6.4. DEVICE DESCRIPTION

LIAISON® XS Analyzer

The DiaSorin LIAISON® XS Analyzer is a fully automated, closed, continuous loading of samples and reagents *in vitro* diagnostic immunoassay system utilizing chemiluminescent technology to provide rapid sample results. The analyzer uses DiaSorin proprietary reagents in which chemiluminescence of an analyte is measured in a sample by the reaction of a magnetic particle solid phase coated with antigen or antibody and a chemiluminescent tracer. The LIAISON® XS Analyzer is intended for use in professional clinical laboratories only.

The general operation of the analyzer is described below.

- The gripper transports the cuvette inside the incubator in which dedicated positions allowed the pipetting of reagents and samples. The incubator is provided with 32 plus 25 positions for the placement of cuvettes.
- At the end of the incubation time, the gripper transports the cuvette from its position in the incubator into the washer with three wash positions. The washer transport mechanism moves the cuvette, using the analyzer time cycle, from one washing station to the next.
- After passing through the washer, the gripper moves the cuvette:
- CASE 1: Return transport for 2-step process

  Back in the incubator for addition of second-step reagent(s). After incubation, the gripper moves back the cuvette in the washer.

- CASE 2: Transport into the measuring chamber for 1-step process

  In the measuring chamber.

- After the measurement, the reaction solution is removed by suction and the cuvette is then automatically disposed of into the waste container.

LIAISON® Anti-HAV Assay

The method for qualitative determination of anti-HAV is a competitive sandwich chemiluminescence immunoassay (CLIA) based on neutralization. The assay uses magnetic particles (solid phase) coated with IgG antibodies to HAV (mouse monoclonal), and a mouse monoclonal anti-HAV antibody conjugate linked to an isoluminol derivative (isoluminol-antibody conjugate). The first incubation step consists of adding the HAV antigen to calibrators, samples or controls, during which anti-HAV present in calibrators, samples or controls binds to a fixed and limited amount of HAV, thus forming an HAV-anti-HAV immune complex. After this step the second incubation follows and it involves addition of magnetic microparticles and conjugate into the cuvette, during which the antibody conjugate and the solid-phase antibody compete with anti-HAV present in the specimen for HAV. This allows the conjugate to bind to the solid phase and to form a sandwich. If all HAV added is sequestered in an HAV-anti-HAV immune complex during the first incubation, no sandwich is formed during the second incubation. After the second incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is inversely indicative of anti-HAV present in calibrators, samples or controls.

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® Anti-HAV assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium

heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in
conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

This assay is not intended for screening blood or solid or soft tissue donors.

6.6 LIAISON XS Analyzer

The test is run on the LIAISON® XS Analyzer which is a Diagnostic System that measures chemiluminescence. It is intended strictly for professional *in-vitro* Diagnostic use. It is to be used only with Chemiluminescence Immunoassays, authorized by DiaSorin S.p.A. for the LIAISON® XS instrument.

6.7. REASON FOR SUBMISSION

This Special 510(k) is being filed to seek FDA clearance for the LIAISON® XS analyzer, a modified version of the existing LIAISON® XS analyzer, which is currently cleared (k193532, FDA cleared on March 2, 2020).

6.8. DESCRIPTION OF DEVICE MODIFICATION

A retrospective analysis of complaints filed on the part of DiaSorin to Stratec, the supplier, highlighted a general poor reliability of the reagent pipettor (right pipettor or SPOLV).
A modification to the device was then devised to improve the reliability, addressing the following areas:

1. Composition of the System Liquid (SL from now on), whose salt and surfactant content was reduced or nullified;
2. Hardware (HW) configuration, adapted to process two different consumables, one for solid phase rinsing in the washer Wash Buffer (WB) and one for the SPOLV line filling and the needle rinsing (SL);
3. Software (SW) and firmware (FW) update, to properly command the new HW parts and provide the user with the relevant information in the user interface for the proper handling of the various supply.

Table 6-1: Describes the changes applied to the LIAISON® XS Analyzer and the handling of the assays run on it.

Assembly[1], accessory or process modified	**Function**	**LIAISON® XS Analyzer (current version cleared as K193532)**	**LIAISON® XS Analyzer modified version**
Formulation of the System Liquid (SL)	The SL fills the reagent pipettor line to: • Transmit the motion of the syringe plunger to the tip of the pipettor probe so to allow reagent aspiration and dispensation,	LIAISON® EASY Wash/System Liquid is used: it is a 10x concentrate diluted by the user with purified water to the concentration of use. It features sodium and potassium chlorides, a phosphate buffer, Tween 20 as a surfactant and sodium azide as a preservative.	LIAISON® EASY System Liquid shall be used: it is a 55.6x concentrate diluted by the user with purified water to the concentration of use. It features sodium and potassium chlorides, a phosphate buffer, and sodium azide as a preservative, at a total solute final concentration of about

[1] An *assembly* is a part of an analyzer presiding a given set of actions, operations or processes. An assembly is capable of operating in time with others in order to exchange materials or objects or data.

	• Cleanse the pipettor during the probe washing cycle from reagent residuals.		25% of that of the LIAISON® EASY Wash/System Liquid.
Canister housing the system liquid	A canister houses the SL in an amount consistent with the typical analyser workload	A 5 L tank placed inside the analyzer connects to the SPOLV line by the means of a valve/docking station device on the bottom of the tank. Liquid from the very same tank is fed to the washer also.	A new 10 L canister is placed outside the system and connected by the means of an aspiration probe from the top to the SPOLV line.
Canister housing the Wash Buffer	A canister houses the WB in an amount consistent with the typical analyser workload	A 5 L tank placed inside the analyzer connects to the Washer line by the means of a valve/docking station device on the bottom of the tank. Liquid from the very same tank is fed to the SPOLV also.	A new 10 L canister is placed outside the system and connected by the means of an aspiration probe from the top to the Washer line.
SPOLV fluidic line	The line receives SL from the relevant tank and feeds it to the SPOLV	A fluidic line originates from the single 5 L tanks. By the mean of a liquid distribution valve, the liquid is fed to a pump that delivers it to the SPOLV. A filtering unit is present between the pump and the SPOLV to prevent particles to reach SPOLV valve.	A fluidic line originates from the dedicated 10 L tank. The liquid distribution valve is suppressed. The liquid is fed to a pump that delivers it to the SPOLV. A filtering unit is present between the tank and the pump to prevent particles to reach SPOLV valve.
Washer fluidic line	The line receives WB from the relevant tank and feeds it to the SPOLV	A fluidic line originates from the single 5 L tanks. The liquid is fed to a pump that delivers it to the washer.	A fluidic line originates from the dedicated 10 L tank. The liquid distribution valve is suppressed. The liquid is fed to a pump that delivers it to the washer.
Deionized water tank	Deionized water is fed to the pump and the SPOLV through a liquid distribution valve.	Deionized water is used to rinse the syringe to remove salt/surfactant based solution when the analyser idles.	As no surfactant based solution is present any longer for the SPOLV, the tank is no longer implemented. The SPOLV syringe is periodically rinsed in SL, a low salt solution.
Analyser main SW and FW	Control the functions of the analyser	The SW/FW is designed to control all the analyser's functions, among those the handling of the liquid consumables resources.	The SW/FW shall be changed to a new version, such to manage the new fluidic layout. Minor anomalies shall be fixed as well
Intended use of LIAISON® EASY Wash/System Liquid	LIAISON® EASY Wash/System Liquid fills the lines to feed SPOLV and Washer	LIAISON® EASY Wash/System Liquid is required on the LIAISON® XS Analyzer to wash the magnetic particles used in LIAISON® immunoassays, as a system liquid, and for rinsing the pipetting needle and tubing system of the LIAISON® XS Analyzer	The same liquid shall be only required on the LIAISON® XS Analyzer to wash the magnetic particles used in LIAISON® immunoassays. As such, the intended use shall be consistently limited and the trade name shall be changed to LIAISON® EASY Wash Buffer

6.9. COMPARISON TO PREDICATE DEVICE

The following table (Table 6-2) provides a summary of the similarities and differences between the predicate device, the LIAISON Anti-HAV run on LIAISON® XS Analyzer (K193532), and the modified device.

The LIAISON® Anti-HAV component and procedures remain unchanged. The following table provides a detailed comparison of parts, implementation and functions for the current and the modified version of the LIAISON® XS analyzer.

Table 6-2: Comparison with the predicate device

Feature	**LIAISON® Anti-HAV (current version LIAISON XS Analyzer cleared as K193532)**	**LIAISON Anti-HAV (LIAISON® XS Analyzer modified version)**
Intended Use	The LIAISON® Anti-HAV assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients. This assay is not intended for screening blood or solid or soft tissue donors.	Same
Principles of operation	Chemiluminescence using magnetic particle solid phase and chemiluminescent tracer	Same
Optical System	High-sensitive, low-noise photomultiplier tube (PMT) operating as an ultra-fast photon counter. Pulses are amplified by a rapid electronic amplifier.	Same
	Circuit that suppresses PMT signal noise.	Same
	Linear measuring range = 300 – 650 nm	Same
	Light peak of chemiluminescence emitted at 450 nm	Same
Temperature Control: Reaction Temperature	36°C±1°C	Same
Temperature Control: Reagent Storage Temperature	11-15°C	Same
Dispense System	Automated pipetting of samples and reagents. Left pipetting unit used for samples; right pipetting unit used for reagents. Sample pipetting: disposable tip	Same
	Precision syringes Left pipetting unit operates an air displacement syringe. Right pipetting unit operates a liquid filled syringe.	Same
	Sample Probe (disposable tip): - Liquid Level Detection and Clot Detection feature (pressure)	Same
	Disposable tips: 2 trays of 96 tips each can be loaded on board. Monitored through software counter and presence sensor upon tip pick-up. Reloading allowed before run, or pausing the ongoing tasks during a routine.	Same
	Reagent Probe:	Same

	- Liquid Level Detection (capacitive), with software tracking of reagent level - Optical Liquid Verification (real-time monitoring of liquid flow inside the probe)	
Sample Handling	Capacity: Holds 4 sample racks, 12 places per rack	Same
	Tube types: - primary tube - aliquot tube - pediatric	Same
	Sample presence, sample type (calibrator, control, patient), tube size, and processing completion tracked by operating software and sample barcode	Same
Reagent Handling	Capacity: 10 Reagent Integrals (RI), plus 4 positions for Ancillary Reagents	Same
	RI contains all reagents required for any given assay (up to 7 vials per RI, first vial always contains magnetic particles).	Same
	Assay-specific processing and analysis parameters, calibration, lot number, expiration date, and usage (number of tests run) are controlled by operating software as communicated by RF-Tag (RF-ID).	Same
Additional Reagents	● Control Set (2 or more levels) ● LIAISON Light Check (diagnostic tool only, reserved for service intervention) ● LIAISON® EASY Starter Kit (Starter Reagents 1 and 2, with different trade name, but the same formulation as Liaison Starter Kit) ● LIAISON® EASY Wash/System Liquid (used as a wash liquid – immunometric wash step and fluidic filler) ● LIAISON® EASY Cleaning Tool.	● Control Set (2 levels) ● LIAISON Light Check (diagnostic tool only, reserved for service intervention) ● LIAISON EASY Starter Kit (Starter Reagents 1 and 2, with different trade name, but the same formulation as Liaison Starter Kit) ● LIAISON® EASY Wash Buffer (used as a wash liquid – immunometric wash step - , with different trade name, but the same formulation as LIAISON® EASY Wash/System Liquid) ● LIAISON® EASY System Liquid (used as a fluidic filler and cleaner of the reagent needle) ● LIAISON® EASY Cleaning Tool.
	In addition: ● Purified water is also required as System Liquid, as fluidic filler and to perform: - reagent needle cleaning - washer needle cleaning ● A cleaning tank is available to host a cleaning liquid suitable for automated maintenance purpose	In addition: ● No purified water is used ● A cleaning tank is available to host a cleaning liquid suitable for automated maintenance purpose
	Level sensor present	Level sensor present as a capacitive rod
Starter reagents	The system can host one set of Starter Reagents. Recognition of Starter Reagents: via RF-Tag	Same
	One bottle of each Starter reagent can be loaded on board	Same
	Injection of Starter Reagents through high precision/accuracy pump (fixed dispensing volume)	Same
	dispense monitoring through optical sensor	Same
	injection of Starter Reagents occurs at controlled temperature (33-37°C)	Same
Reaction Modules	Capacity: Single-cavity Cuvettes	Same
	Storage capacity: up to 172 cuvettes	Same
	Same	Same
	Reloading allowed before run, or pausing the ongoing tasks during a routine	Same
	Unloading automatic into waste container	Same

Test Processing	Random Access and Batch	Same
	Continuous operation	Same
	Sample scheduling optimized for throughput	Same
Assay Protocols	1-Step assays: 1 incubation sequence / 1 wash sequence; average incubation time = 10 minutes	Same
	2-Step assays: 2 incubation sequence / 1 or 2 wash sequence(s); average incubation time = 10 minutes	Same
	Two-point and one-point calibration of assays	Same
Human Interface	Same	Same
	Touch-screen On Screen Keyboard (keyboard and mouse not supplied)	Same
	Same (integrated with the computer)	Same
	Printer (optional)	Same
	Stationary barcode scanner for identification of samples. Stationary RF-Tag reader for identification of reagents. (Reagent Integrals and Starter Reagents). Handheld barcode scanner for identification of controls.	Same
	Computer LIS Interface	Same
Data Analysis	Automated data reduction	Same
	Assay-specific Master Curve with two-point or one-point recalibration	Same
	Assay-specific data reduction	Same
Specimens	Serum or plasma or other body fluids or their extract	Same
	Sampling from primary, aliquot, or pediatric tubes	Same
Disposables	Reagent Integrals	Same
	Light Check (tool for service intervention only)	Same
	LIAISON® EASY Wash/System Liquid	LIAISON® EASY Wash Buffer Same chemical formulation, different trade name
	Not present	LIAISON® EASY System Liquid
	Cuvettes	Same (same as LIAISON® XL but in dedicated trays)
	Disposable Tips	Same
	Waste box, single use (dedicated)	Same
	Cleaning Kit(dedicated)	Same
Software	Based on: ● Windows	Same
Hardware	● Bench-top, integrated design (PC, monitor, keyboard are integrated in the design) ● average throughput optimized for medium/small laboratories ● Data exchange for Reagent Integrals, Ancillary Reagents, Starter Reagents via RF-ID technology: higher data exchange, higher reagent traceability allowed ● Disposable tip for sample pipetting	Same with the following design optimization: ● External 10 L canisters to house separately diluted LIAISON® EASY Wash Buffer and LIAISON® EASY System Liquid ● Changes in the liquid supply lines connected with the external tanks
Software	Software version 1.3.3 SP2	Software version 1.3.7. It integrates the changes needed to support the use of the two external tanks and minor bug fixing from the previous version.

6.10. 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.

6.11. 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.

6.12. SUMMARY OF PERFORMANCE DATA

Immunometrical performance was assessed as in the original 510(k) for what is described in Table 6-3 with the assay LIAISON® anti-HAV.

Table 6-3: Summary of Immunometrical performance assessment

Parameter	Acceptance criteria	Found	Acceptance criteria met?
Analytical Sensitivity, as concentration at cut off threshold vs WHO standard preparation	Analytical sensitivity in the range 15.5 - 21.5 mIU/ml	Run 1: 21 mIU/mL Run 2: 20 mIU/mL	Yes
Total precision, as value of the percentage coefficient of variation (CV)	≤14.5%	3.3 – 7.2%	Yes
Positive agreement	≥95%	97.0%	Yes
Negative agreement	≥95%	98.2%	Yes

All items relevant for the software were successfully verified and validated.
All items relevant for the hardware were successfully verified and validated.

6.13. SUBSTANTIAL EQUIVALENCE STATEMENT

All verification and validation testing conducted with the LIAISON Anti-HAV run on the LIAISON® XS Analyzer 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 Anti-HAV run on the LIAISON® XS analyzer is substantially equivalent to the predicate device.

6.14. CONCLUSION

The material submitted in this Special 510(k): Device Modifications of the LIAISON® Anti-HAV run on the LIAISON XS Analyzer (k1293532) is complete and supports a substantial equivalence decision. The labeling satisfies the requirements of 21 CFR 809.10.