December 9, 2022

DiaSorin Inc.
Kerrie Oetter
Director, Regulatory Affairs
1951 Northwestern Ave.
P.O. Box 285
Stillwater, Minnesota 55082

Re: K223403
Trade/Device Name: LIAISON Anti-HAV; LIAISON XS
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Assays
Regulatory Class: Class II
Product Code: LOL
Dated: November 8, 2022
Received: November 9, 2022

Dear Kerrie Oetter:

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 I. Garcia -S

Maria Garcia, Ph.D.
Assistant Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K223403

Device Name
LIAISON Anti-HAV
LIAISON XS

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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510(k) Summary **K223403**

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Date prepared: December 8, 2022

Name of device:

Trade Name:	LIAISON® Anti-HAV; LIAISON® XS
Common Name:	Hepatitis Anti-HAV, serological assay; Automated Chemiluminescent Immunoassay Analyzer
Classification Name:	Hepatitis A Test (antibody and IgM antibody): Class II, 21 CFR 866.3310; Microbiology; Analyzer, Chemistry, Micro, For Clinical Use: Class I, 21 CFR 862.2170; Microbiology, Clinical
Product Code:	LOL JJF

Predicate Device: LIAISON® Anti-HAV, LIAISON® XS (K210272)

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.

Intended Use/Indications for Use

The Intended Use/Indications for Use of the device as described in its current labeling (K210272) has not changed as a result of the modifications.

The LIAISON® XS Analyzer 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 Italia S.p.A. for the LIAISON® XS instrument.

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.

Comparison to Predicate Device

The device configuration of the LIAISON® XS Analyzer was modified to return it to the initial configuration (cleared under K193532) where onboard canisters for the supply of liquids are moved back onboard the Analyzer. These modifications include:

1. Hardware (HW) configuration, adapted to the new onboard canisters;
2. Firmware (FW) and Software (SW), adapted to support the re-arranged HW and provide proper information about the various supplies in the main User Interface;
3. New version of Wash Buffer consumable, adapted to the new onboard canister.

A comparison of the similarities and differences between the devices is provided in the following table.

Table 1: Comparison of the LIAISON® XS Analyzer with the predicate device

Feature	LIAISON® XS Analyzer (current version cleared as K210272)	LIAISON® XS Analyzer modified version
Intended Use	Automated chemiluminescent analyzer for clinical use	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 onboard. 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: - Liquid Level Detection (capacitive), with software tracking of reagent level - Optical Liquid Verification (real-time monitoring of liquid flow inside the probe)	Same
Sample Handling	Capacity: Holds 4 sample racks, 12 places per rack	Same
	Tube types: - primary tube - aliquot tube - pediatric	Same

Feature	LIAISON® XS Analyzer (current version cleared as K210272)	LIAISON® XS Analyzer modified version
	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 levels) ● LIAISON Light Check (diagnostic tool only, reserved for service intervention) ● LIAISON® EASY Cleaning Tool	Same
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 Buffer	Only difference is that LIAISON® EASY Wash Buffer is supplied in bottles with 300 mL filling volume instead of 500 mL filling volume. Product code and chemical formulation are the same.
	LIAISON® EASY System Liquid	Same
	LIAISON EASY Starter Kit	Same
	Cuvettes	Same

Feature	LIAISON® XS Analyzer (current version cleared as K210272)	LIAISON® XS Analyzer modified version
	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: ● Internal 5 L canister to house diluted LIAISON® EASY System Liquid ● Internal 3L canister to house LIAISON® EASY Wash Buffer ● Changes in the liquid supply lines connected to the new internal canisters
Software	Software version 1.4.9	Software version 1.5.2. It integrates the changes needed to support the use of the two internal tanks and minor bug fixing from the previous version.

Summary of Performance Data

Non-clinical verification and validation activities conducted with the LIAISON® XS Analyzer demonstrate that the modified device met predetermined acceptance criteria, supporting equivalency of the modified device to the cleared device. All verification and validation activities were performed in accordance with 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. Evidence is demonstrated through the following studies:

- Non-regression testing of immunometrical performance
- Hardware reliability evaluation
- Usability testing
- Software verification and validation

Based on the results from the verification and validation activities, the modifications to the LIAISON® XS Analyzer do not introduce any new risks to the performance of the device and do no alter safety and effectiveness.

Conclusion

The material submitted in this premarket notification is complete and supports a determination of substantial equivalence to the previous System configuration. The labeling is sufficient and satisfies the requirements of 21 CFR 809.10.