June 4, 2026

DiaSorin, Inc.
Elauteria Earnhardt
Regulatory Affairs Specialist
1951 Northwestern Ave.
Stillwater, Minnesota 55082

Re: K260770
Trade/Device Name: LIAISON Murex HBsAg Qual; LIAISON XL; LIAISON diluteX
Regulation Number: 21 CFR 866.3172
Regulation Name: Qualitative hepatitis B virus antigen assays
Regulatory Class: Class II
Product Code: LOM, JJF
Dated: March 9, 2026
Received: March 9, 2026

Dear Elauteria Earnhardt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

UWE SCHERF -S

Uwe Scherf, M.Sc., Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260770

Device Name
LIAISON® Murex HBsAg Qual;
LIAISON® diluteX;
LIAISON® XL

Indications for Use *(Describe)*

LIAISON® Murex HBsAg Qual

The LIAISON® Murex HBsAg Qual assay is an in vitro chemiluminescent immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) including separator tubes, on the LIAISON® XL and LIAISON® XS Analyzers. Assay results in conjunction with other hepatitis B virus (HBV) serological and clinical information, may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. This assay is not approved for use in screening blood, plasma or tissue donors.
Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.

LIAISON® diluteX

The LIAISON® diluteX is an accessory for the LIAISON® XL analyzer.
It is designed to automatically dilute the LIAISON® Wash/System Liquid with purified water and to distribute both the purified water and the diluted Wash/System Liquid (referred to as "Wash Buffer") to each connected LIAISON® XL. The LIAISON® diluteX utilizes purified water (referred to as "sourced water"), which must be supplied to the device. The device automatically dilutes the LIAISON® Wash/System Liquid, stored on the device, with the sourced water and distributes both the diluted Wash/System Liquid and the sourced water to the LIAISON® XL via separate tubes directly into the analyzer's tanks.
For professional use only.

LIAISON® XL

The LIAISON® XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for in vitro diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer.
It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON® XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

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

Submitted by:
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Date prepared: March 13, 2026

Name of device:

Trade Name: LIAISON® Murex HBsAg Qual
LIAISON® XL
LIAISON® diluteX

Common Name: Test, Hepatitis B (B Antigen, B Surface Antigen)

Classification Name: Class II, 21 CFR 866.3172: Qualitative hepatitis B virus antigen assays;
Class I, 21 CFR 862.2170: Micro chemistry analyzer for clinical use;

Clinical Use:

Product Code: LOM
JJF

Predicate Device: LIAISON® Murex HBsAg Qual (P190017)
LIAISON® XL (K141116)

Device Description

LIAISON® Murex HBsAg Qual

The method for qualitative determination of HBsAg is a direct sandwich chemiluminescence immunoassay (CLIA). A mixture of mouse monoclonal antibodies is used for coating magnetic particles (solid phase) and a different mixture of mouse monoclonal antibodies directed to different epitopes is linked to an isoluminol derivative (isoluminol-antibody conjugate).
During the first incubation, HBsAg present in calibrators, samples or controls binds to the solid phase. During the second incubation, the antibody conjugate reacts with HBsAg already bound to the solid phase. After 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 directly proportional to HBsAg concentration present in calibrators, samples or controls.

LIAISON® diluteX
The LIAISON diluteX is an accessory for the LIAISON® XL analyzer.

The LIAISON® diluteX interfaces with the LIAISON® XL analyzer in order to automatically fill the LIAISON® XL tanks with purified water and properly pre-diluted LIAISON® Wash/System Liquid (code 319100). The LIAISON® diluteX enables automatic dilution of the LIAISON® Wash/System Liquid in a range between 1 to 9.5/10.5 from the more concentrated bottled LIAISON® Wash/System liquid. An accurate fluidic system controlled by pressure regulators, pumps, valves and tubes allows the diluted solution to go out of the system and reach the LIAISON® XL analyzer. By the usage of customized caps installed on the LIAISON® XL analyzer, the LIAISON® diluteX is able to automatically refill the diluted solution in the Wash Buffer tank of the LIAISON XL analyzer. In the same way, the LIAISON® diluteX is able to refill the deionized water tank of LIAISON® XL analyzer

Intended Use/Indications for Use

The Intended Use/Indications for Use of the device as described in its current labeling (P190017) has not changed as a result of the modifications.

LIAISON® Murex HBsAg Qual
The LIAISON® Murex HBsAg Qual assay is an in vitro chemiluminescent immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) including separator tubes, on the LIAISON® XL and LIAISON® XS Analyzers. Assay results in conjunction with other hepatitis B virus (HBV) serological and clinical information, may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. This assay is not approved for use in screening blood, plasma or tissue donors.
Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.

LIAISON® diluteX
The LIAISON® diluteX is an accessory for the LIAISON® XL analyzer.
It is designed to automatically dilute the LIAISON® Wash/System Liquid with purified water and to distribute both the purified water and the diluted Wash/System Liquid (referred to as "Wash Buffer") to each connected LIAISON® XL. The LIAISON® diluteX utilizes purified water (referred to as "sourced water"), which must be supplied to the device. The device automatically dilutes the LIAISON® Wash/System Liquid, stored on the device, with the sourced water and distributes both the diluted Wash/System Liquid and the sourced water to the LIAISON® XL via separate tubes directly into the analyzer's tanks.
For professional use only.

LIAISON® XL

The LIAISON® XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for in vitro diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer.

It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON® XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

Comparison to Predicate Device

The proposed change in this Traditional 510(k) is the introduction of an alternative method for supplying purified water and Wash Buffer to the LIAISON® XL Analyzer (LXL) for use with the LIAISON® assays, including LIAISON® Murex HBsAg Qual assay.

Table 1: Comparison of current process and new process - differences and similarities with the predicate device

Task, step or action	**LIAISON Murex HBsAg Qual with manual process LIAISON® XL, P190017/S018 (Predicate device)**	**LIAISON Murex HBsAg Qual with automated process by means of diluteX LIAISON® XL connected to diluteX**
Purified Water supply Provision of purified water to the LXL, upon the liquid level reaching a lower threshold in the tank on board the LXL	The LXL signals by means of a display on the GUI the shortage of purified water; The user accesses the lower cabinet and disconnects the purified water tank from the intermediate tank; The user moves the tank to a purified water faucet; The user fills the tank at the purified water faucet; The user returns the tank to cabinet and reconnect it to the LXL; The LXL detects the increased liquid level; The whole process is possible without interruption of the LXL operation, provided the refilling is faster than the exhaustion of the intermediate tank internal to the LXL. Otherwise, The LXL may need more purified water than the residual in the intermediate tank. The LXL SW shall then independently halt the progression of the routine, before any failure in the purified water provision happens.	The diluteX is connected to a purified water source by a dedicate tube; The diluteX, by means of a sensor of its own in the purified water tank of the LXL and completely independent from the LXL, detects the liquid level below a lower threshold; The diluteX then automatically opens a set of valves, allowing the purified water flowing directly from the faucet to the canister by the tube line connected to the LXL tank; The independent sensor in the canister monitors the liquid level until it reaches an upper threshold; At this point, the diluteX switches the valve set and stops the purified water flow; The whole process is possible without interruption of the LXL operation. Errors in feeding are monitored by the independent SW of the diluteX. In case these are such to limit a satisfactory provision of purified water, the LXL SW shall independently halt the progression of the routine, before any failure in the purified water provision happens. In fact, being the two devices operated by completely independent SWs, each of them retains the whole suite of in process controls typical of

		the specific SW.
Wash Buffer Detection of the liquid level reaching a lower threshold in the tank on board the LXL	The LXL signals by means of a display on the GUI the shortage of Wash Buffer.	The diluteX, by means of a sensor of its own in the tank completely independent from the LXL, detects the liquid level below a lower threshold.
Wash Buffer Preparation of the Wash Buffer from the concentrate	The user accesses the lower cabinet and disconnects the Wash Buffer tank from the intermediate tank; The user manually empties the tank of the remnant of Wash Buffer; The user moves the tank to a purified water faucet; The user rinses the tank and fills the tank at the purified water faucet up to the mark (9 L); The user slowly pours the whole content of a 1 L bottle of LIAISON® Wash/System Liquid in the Wash Buffer tank; The user allows a waiting time of 6 hour to homogenize and degas, with the cap loosely screwed on the tank.	The diluteX is connected to a purified water source by a dedicate tube; The user pours in the LIAISON® Wash/System Liquid tank on the diluteX up to 5 bottles, 1 L each, of concentrate solution; The diluteX, by means of a sensor of its own in the tank completely independent from the LXL, detects the liquid level below a lower threshold; The diluteX automatically opens a set of valves directing the purified water to the dilution pump; The diluteX automatically opens a set of valves directing the LIAISON® Wash/System Liquid to the dilution pump; The dilution pumps add both liquids in a predefined fixed mixing ratio (1 part of the

		LIAISON® Wash/System Liquid and 9 of purified water) to a mixing line and Wash Buffer intermediate tank. Mixing line and intermediate tank are laid out in a way such that full homogenization is immediately achieved, preventing foam development at the same time. Therefore, the 6-hour waiting time is not needed any longer.
Wash Buffer Provision of the Wash Buffer to the LXL	After the 6 hour of waiting time elapsed, the user tightens the cap, returns the filled tank to cabinet and reconnects it to the LXL; The LXL detects the increased liquid level. The whole process is possible without interruption of the LXL operation, provided a second prefilled tank is already available when the former is disconnected. Otherwise, during the 6 hour waiting time, the LXL may need more Wash Buffer than the residual in the intermediate tank internal to the LXL. The LXL SW shall then independently halt the progression of the routine, before any failure in the Wash Buffer provision happens.	The diluteX then automatically opens a set of valves, allowing the Wash Buffer to flow directly from the intermediate tank to the canister by the tube line connected to the LXL tank; The independent sensor in the canister monitors the liquid level until it reaches an upper threshold; At this point, the diluteX switches the valve set, stops the dilution pump and stops the Wash Buffer flow; The whole process is possible without interruption of the LXL operation. Errors in the feeding are monitored by the independent SW of the diluteX. In case these are such to limit a satisfactory provision of Wash Buffer, the LXL SW shall independently halt the progression of the routine, before any failure in the Wash Buffer provision happens. In fact, being the two devices operated by completely independent SWs, each of them retains the whole suite of in process controls typical of the specific SW.
Use of the LIAISON® Wash/System Liquid	The LIAISON® Wash/System Liquid is delivered to the user in 1 L plastic bottles. When needed, a single bottle is opened and carefully poured in a Wash Buffer tank already filled with 9 L of purified water.	The LIAISON® Wash/System Liquid is delivered to the user in 1 L plastic bottles. The content of up to five plastic bottles, for an overall volume of 5 L, can be poured in the dedicate tank on the diluteX. The content of the tank is stable for twenty-eight (28) days and a SW driven maintenance task prompts the user to empty, rinse and fill again with liquid from new bottles the tank at the expiration of the 28-day span.

No modification is introduced in the LIAISON® Murex HBsAg Qual device or in any other LIAISON® Assay as a part of this change.

Summary of Performance Data

Non-clinical verification and validation activities conducted with the LIAISON® XL analyzer interfaced with the LIAISON® diluteX 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:

- Method comparison
- Precision testing
- Wash efficiency (Analyte Carry Over)
- Real Life Testing

Conclusion

The material submitted in this 510(k) 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.