Diasorin Inc.
% Kerrie Oetter
Director, Regulatory Affairs
1951 Northwestern Ave.,
Stillwater, MN 55082 USA

December 23, 2025

Re: DEN250032
Trade/Device Name: LIAISON XL MUREX Anti-HDV
Regulation Number: 21 CFR 866.3176
Regulation Name: Device to detect antibodies to hepatitis D Virus
Regulatory Class: Class II
Product Code: SGW
Dated: July 30, 2025
Received: July 30, 2025

Dear Kerrie Oetter:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of LIAISON XL MUREX Anti-HDV, a prescription device with the following indications for use:

> The LIAISON XL MUREX Anti-HDV assay uses chemiluminescence immunoassay (CLIA) technology for the qualitative detection of antibodies to the hepatitis D virus (anti-HDV) in adult human serum, lithium, sodium heparin, and K2-EDTA plasma. The assay is intended as an aid in the presumptive diagnosis of HDV infection in individuals who are HBsAg positive and at risk for HDV infection. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide evidence of infection with HDV. This test does not determine the state of infection or associated disease.
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> The test must be performed on the LIAISON XL Analyzer.
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> The LIAISON XL MUREX Control Anti-HDV (negative and positive) are intended for use as assayed quality control samples to monitor the performance and reliability of LIAISON XL MUREX Anti-HDV assay. The performance characteristics of LIAISON XL MUREX Anti-HDV controls have not been established for any other assays or instrument platforms different from LIAISON XL Analyzer.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies LIAISON XL MUREX Anti-HDV, and substantially equivalent devices of this generic type, into Class II under the generic name device to detect antibodies to hepatitis D virus.

FDA identifies this generic type of device as:

> **Device to detect antibodies to hepatitis D virus.** The device to detect antibodies to hepatitis D Virus is an in vitro diagnostic device intended for prescription use for the detection of antibodies to the hepatitis D virus (anti-HDV) in human clinical specimens. The assay is intended as an aid in the diagnosis of HDV infection in individuals who are at risk for HDV infection. The assay is intended as an aid in diagnosis in conjunction with clinical findings and other diagnostic procedures. The assay is not intended for screening of blood, plasma, cells, or tissue donors.

Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a riskbased classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 30, 2025, FDA received your De Novo requesting classification of LIAISON XL MUREX Anti-HDV. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify LIAISON XL MUREX Anti-HDV into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the LIAISON XL MUREX Anti-HDV device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
False reactive/false non-reactive assay result	Certain labeling information, warnings, limitations, results interpretation information, and explanation of procedures. Certain design verification and validation information, including analytical and clinical studies and risk analysis strategies.
Failure to correctly interpret the assay results	Certain labeling information, warnings, limitations, results interpretation information, and explanation of procedures. Certain design verification and validation information, including analytical and clinical studies and risk analysis strategies.

Failure to correctly operate the device	Certain labeling information, warnings, limitations, results interpretation information, and explanation of procedures. Certain design verification and validation information, including analytical and clinical studies and risk analysis strategies.

In combination with the general controls of the FD&C Act, the device to detect antibodies to hepatitis D virus is subject to the following special controls:

(1) The labeling required must include:
  (i) A prominent statement that the assay is not intended for the screening of blood, plasma, cells, or tissue donors.
  (ii) A detailed explanation of the principles of operation and procedures for performing the assay.
  (iii) A detailed explanation of interpretation of results.
  (iv) Limitations, which must be updated to reflect current clinical practice and disease presentation and management. The limitations must include statements that indicate:
    (A) The specimen types for which the device has been cleared, and that use of the assay with specimen types other than those specifically cleared for this device may result in inaccurate assay results.
    (B) When appropriate, performance characteristics of the assay have not been established in populations of immunocompromised or immunosuppressed patients or other populations where assay performance may be affected.
    (C) Detection of HDV antibodies indicates a current or past infection with hepatitis D virus, but does not differentiate between acute, chronic, or resolved infection.
    (D) Diagnosis of hepatitis D infection should not be established on the basis of a single assay result but should be determined by a licensed healthcare professional in conjunction with clinical presentation, history, and other diagnostic procedures.
    (E) A non-reactive assay result may occur early during acute infection, prior to development of a host antibody response to infection, or when analyte levels are below the limit of detection of the assay.
    (F) Results obtained with this assay may not be used interchangeably with results obtained with a different manufacturer's assay.

(2) Design verification and validation must include the following:
  (i) Detailed device description, including all parts that make up the device, ancillary reagents required but not provided, an explanation of the device methodology, and design of the antigen(s) and capture antibody(ies) sequences, rationale for the selected epitope(s), degree of amino acid sequence conservation of the target, and the design and composition of all primary, secondary, and subsequent standards used for calibration.
  (ii) Documentation and characterization (e.g., supplier, determination of identity, purity and stability) of all critical reagents (including description of the antigen(s) and capture antibody(ies)), and protocols for maintaining product integrity throughout its labeled shelf life.

(iii) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on assay performance.
(iv) Stability studies for reagents that include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.
(v) Detailed documentation of analytical performance studies and results for determining limit of detection (LoD), cutoff, precision, including lot-to-lot and instrument-to-instrument precision, multi-site reproducibility, interference, cross reactivity, carryover, hook effect, matrix equivalency, specimen stability, reagent stability, and genotype antibody detection sensitivity, when appropriate.
(vi) Detailed documentation of acceptable clinical performance testing from a clinical study with an appropriate number of HDV reactive and non-reactive samples in applicable categories and conducted in the appropriate settings by the intended users. Performance must be analyzed relative to an FDA cleared or approved HDV antibody assay or a comparator that FDA has determined is appropriate. Additional relevant patient groups must be validated as appropriate. The samples must include samples for each identified specimen type and, as appropriate, additional characterized clinical samples. Samples must be sourced from geographically diverse areas. This study must be conducted in the appropriate settings by the intended users to demonstrate clinical performance.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the device to detect antibodies to hepatitis D virus they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Kathleen B. Whitaker at 301-796-6208.

Sincerely,

Uwe Scherf -S

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