Roche Diagnostics
Lisa Klinedinst
Senior Regulatory Affairs Program Manager
9115 Hague Rd.
Indianapolis, Illinois 46250

October 20, 2026

Re: DEN260027
Trade/Device Name: Elecsys HBsAg II quant II RxDx
Regulation Number: 21 CFR 866.3177
Regulation Name: Quantitative hepatitis B virus surface antigen test
Regulatory Class: Class II
Product Code: SJM
Dated: May 29, 2026
Received: June 2, 2026

Dear Lisa Klinedinst:

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 the Elecsys HBsAg II quant II RxDx, a prescription device with the following indications for use:

> The Elecsys HBsAg II quant II RxDx immunoassay is an in vitro electrochemiluminescence immunoassay for the quantitation of hepatitis B surface antigen (HBsAg) in serum and plasma from patients with chronic HBV infection.
> The Elecsys HBsAg II quant II RxDx immunoassay is intended for use as an aid in the selection of patients 18 years and older with chronic HBV infection for treatment with antiviral therapy in accordance with the FDA approved drug labeling and as an aid in management of patients undergoing antiviral therapy. The assay can be used to measure HBsAg levels at baseline, during treatment and at the end of treatment to aid in assessing response to therapy. The results of the Elecsys HBsAg II quant II RxDx immunoassay must be interpreted within the context of all relevant clinical and laboratory findings.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Elecsys HBsAg II quant II RxDx, and substantially equivalent devices of this generic type, into Class II under the generic name quantitative hepatitis B virus surface antigen test.

FDA identifies this generic type of device as:

Quantitative hepatitis B virus surface antigen test. A quantitative hepatitis B virus (HBV) surface antigen (HBsAg) test is an in vitro diagnostic device intended for prescription use for the quantitative determination of HBsAg in human serum, plasma, or other matrices specimens from individuals with HBV infection as an aid in the management of HBV-infected individuals including identifying patients who may benefit from treatment with appropriate antiviral therapies in accordance with the approved therapeutic product labeling.

Section 513(f)(2) of the 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 risk-based 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 June 2, 2026, FDA received your De Novo requesting classification of the Elecsys HBsAg II quant II RxDx. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Elecsys HBsAg II quant II RxDx 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 Elecsys HBsAg II quant II RxDx 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:

Risks to Health	**Mitigation Measures**
Falsely elevated/falsely lowered 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	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 quantitative hepatitis B virus surface antigen test is subject to the following special controls:

1. 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 capture antibody(ies), external controls, and computational path from collected raw data to reported result (e.g., how collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design.
   (ii) Documentation of the design and composition of all primary, secondary, and subsequent quantitation standards used for calibration, as well as their traceability to a standardized reference material that FDA has determined is appropriate (e.g., a recognized consensus standard). In addition, analytical testing must be performed following the release of a new lot of the standard material used for device clearance or approval, or when there is a transition to a new calibration standard.
   (iii) Documentation and characterization (e.g., supplier, determination of identity, purity and stability) of all critical reagents (including description of the capture antibody(ies)), and protocols for maintaining product integrity throughout its labeled shelf life.
   (iv) Documentation of risk analysis and management strategies, including Failure Modes Effects Analysis (FMEA) and/or Hazard Analysis and Critical Control Points (HACCP) summaries and their impact on assay performance.
   (v) Detailed documentation of analytical performance studies and results for determining the limit of blank, limit of detection, upper and lower limits of quantitation, linearity, precision, reproducibility, endogenous and exogenous interferences, cross-reactivity, interference, carryover, hook effect, seroconversion panel testing, prominent mutants/variants/genotype quantitation, matrix equivalency and sample stability as applicable. Samples selected for use must be from subjects with clinically relevant circulating genotypes in the United States. Cross-reactivity and microbial interference studies must include samples with other viral or non-viral causes of liver disease, including autoimmune hepatitis, alcoholic liver disease, chronic hepatitis C virus, primary biliary cirrhosis, and steatotic liver disease, where applicable.
   (vi) Clinical data generated using well-characterized clinical specimens representative of the intended use population demonstrating appropriate clinical performance of the device for its intended use, as determined to be appropriate by FDA.

2. Labeling must include:
   (i) A prominent statement that the assay is not intended for the screening of blood, plasma, cells, or tissue donors.

(ii) An appropriate summary, as determined by FDA, of the performance studies performed and the results of those studies, including those required in special control (1).

(iii) 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 this assay with specimen types other than those specifically cleared may result in inaccurate results.

(B) Where appropriate, that performance characteristics have not been established in immunocompromised or immunosuppressed patient populations or other populations where assay performance may be affected.

(C) Management of patients undergoing HBV treatment should not rely on a single assay result but should be determined by a licensed healthcare professional in conjunction with clinical presentation, history, and other diagnostic procedures (e.g., HBV DNA testing, liver function assays, liver elastography, etc.).

(D) Results obtained with this assay may not be used interchangeably with results obtained with a different manufacturer's assay.

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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).

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 quantitative hepatitis B virus surface antigen test 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 Management

System Regulation (QMSR) (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,

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