November 10, 2026

Roche Diagnostics Operations
Leslie Patterson
Senior Regulatory Affairs Manager
9115 Hague Rd.
Indianapolis, Indiana 46250

Re: DEN250070
Trade/Device Name: cobas pro i 601 platform
Regulation Number: 21 CFR 862.1105
Regulation Name: Automated chromatography mass spectrometry platform
Regulatory Class: Class II
Product Code: SJX
Dated: August 26, 2026
Received: August 27, 2026

Dear Leslie Patterson:

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 cobas pro i 601 platform, a prescription device with the following indications for use:

> The cobas pro i 601 platform is an automated liquid chromatography-tandem mass spectrometer based platform intended for in vitro diagnostic use to measure small compounds in human specimens for clinical use. Analytes are identified by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass-to-charge ratio. For the indications of specific analytes that can be measured by the platform, refer to Table 1 in the Device Description.
>
> As listed in Table 1:
> Ionify Gabapentin is part of the automated cobas i 601 platform. It uses liquid chromatography-tandem mass spectrometry (LC-MS/MS) technology for the quantitative determination of gabapentin in human serum and plasma. The determination of gabapentin is used in the diagnosis and treatment of gabapentin overdose and in monitoring levels of gabapentin to ensure appropriate therapy.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the cobas pro i 601 platform, and substantially equivalent devices of this generic type, into Class II under the generic name automated chromatography mass spectrometry platform.

FDA identifies this generic type of device as:

> **Automated chromatography mass spectrometry platform.** An automated chromatography mass spectrometry platform is an in vitro diagnostic device including integrated hardware, software, reagents, calibrators, and chromatography columns. The platform is intended for use in clinical laboratories to quantitatively measure specified individual analytes in clinical specimens for use in the assessment of disease or other conditions to support diagnosis or patient management.

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 December 19, 2025, FDA received your De Novo requesting classification of the cobas pro i 601 platform. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the cobas pro i 601 platform 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 cobas pro i 601 platform 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
Incorrect test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.
Incorrect interpretation of test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.

In combination with the general controls of the FD&C Act, the automated chromatography mass spectrometry platform is subject to the following special controls:

(1) Design verification and validation must include:
  (i) Data demonstrating appropriate validation of the platform workflow demonstrating that all integrated components function appropriately together.
  (ii) Device performance data demonstrating appropriate analytical performance of the device for its intended use, as determined to be appropriate by FDA, including all indications for use, all intended testing environments, intended patient populations, and sample types. These must include the following, or alternatively, justification for an alternative approach must be provided and determined to be appropriate by FDA:
    (A) Analytical validation data including precision, accuracy, specificity (including interference data), and sensitivity (including limit of detection and limit of quantitation). Studies generating these data must be adequate to validate both the analytical measuring interval and relevant medical decision level(s).
    (B) Evidence establishing reference intervals and medical decision levels (e.g., screening cutoffs, therapeutic ranges), as applicable, such as data from a robust reference range study.
  (iii) For each device output, evidence must be provided that adequately demonstrates clinical validity which must include documentation that the analyte(s) being measured is clinically associated with its indication(s) and documentation of established medical decision level, therapeutic ranges, or clinical action thresholds, as applicable to the indications.
(2) Labeling must include, for each device output, a summary of the evidence establishing the reference intervals and medical decision levels required under paragraph 1(ii)(B), including concentrations relevant for clinically relevant subgroups in the intended use population as applicable, for each analyte and medical decision levels.

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. FDA's granting of your De Novo request also included the review and authorization of your Predetermined Change Control Plan (PCCP), IONIFY PREDETERMINED CHANGE CONTROL PLAN FOR THE COBAS PRO I 601 PLATFORM (IONIFY PCCP), Version 3.14. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the authorized PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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).

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 automated chromatography mass spectrometry platform 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); 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 Joseph Cleveland at Joseph.Cleveland@fda.hhs.gov.

Sincerely,

MARIANELA PEREZ-TORRES -S

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