November 10, 2026

Siemens Healthcare Diagnostics, Inc.
Ayu Sucipto
Regulatory Affairs Professional
511 Benedict Ave.
Tarrytown, New York 10591

Re: DEN250069
Trade/Device Name: Atellica IM Neurofilament Light Chain (NfL)
Regulation Number: 21 CFR 866.5845
Regulation Name: Neurological disease activity risk assessment system
Regulatory Class: Class II
Product Code: SBV
Dated: December 19, 2025
Received: December 19, 2025

Dear Ayu Sucipto:

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 Atellica IM Neurofilament Light Chain (NfL), with the following indications for use:

> The Atellica IM Neurofilament Light Chain (NfL) assay is for in vitro diagnostic use in the measurement of neurofilament light chain (NfL) in human serum and plasma (EDTA) using the Atellica IM Analyzer.
>
> The Atellica IM NfL assay, in conjunction with clinical, imaging, and laboratory findings, is intended to be used as an aid in the evaluation of ongoing Multiple Sclerosis (MS) disease activity in patients between 18-55 years of age with Relapsing-Remitting MS (RRMS).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Atellica IM Neurofilament Light Chain (NfL), and substantially equivalent devices of this generic type, into Class II under the generic name neurological disease activity risk assessment system.

FDA identifies this generic type of device as:

> **Neurological disease activity risk assessment system**. A neurological disease activity risk assessment system is a prescription in vitro diagnostic device intended to detect or measure protein biomarkers by immunochemical techniques in clinical specimens to aid in the evaluation of disease

activity, management, or progression in patients with an established neuroinflammatory or neurodegenerative disease, in conjunction with other clinical, laboratory, and radiological findings. This device is not intended to aid in the diagnosis of neuroinflammatory or neurodegenerative disease.

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 Atellica IM Neurofilament Light Chain (NfL). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Atellica IM Neurofilament Light Chain (NfL) (11553991) 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 Atellica IM Neurofilament Light Chain (NfL) 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: • False positive results leading to inappropriate assessments or treatment decisions. • False negative results that may lead to delays or missed opportunities to identify ongoing disease activity.	Certain design verification and validation activities, including certain clinical studies. Certain labeling information, including certain warnings and performance information.

In combination with the general controls of the FD&C Act, the neurological disease activity risk assessment system is subject to the following special controls:

(1) Design verification and validation must include:

(i) An adequate traceability plan to minimize the risk of drift in the analyte(s) measured by the device over time.

(ii) Device performance data demonstrating analytical performance for intended use specimen type(s), including precision and reproducibility, detection limit of the device, linearity, assay interference, cross-reactivity, specimen stability, and analytical accuracy studies, for single and multi-component biomarkers, as determined to be appropriate by FDA.

(iii) Clinical validation testing demonstrating clinical performance of the device for its intended use, as determined to be appropriate by FDA. The clinical studies must use specimens representative of the intended use population.

(2) The labeling must include:

(i) A limiting statement that the test does not determine the patient's overall risk of neurological disease activity.

(ii) A limiting statement that the test is not for use in the diagnosis of the target neuroinflammatory or neurodegenerative disease(s).

(iii) An appropriate summary, as determined by FDA, of the performance studies conducted and the results of those studies, including those that relate to all design verification and validation special controls

(iv) A description of the device detection targets.

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 neurological disease activity risk assessment system 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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 Matthew Butcher at 301-796-0784.

Sincerely,

Takeesha Taylor-Bell

Takeesha Taylor-Bell
Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health