June 12, 2025

Firalis SA
Huseyin Firat
CEO
35 rue du Fort
Huningue, 68330
France

Re: DEN240032
Trade/Device Name: APO-Easy Genotyping kit
Regulation Number: 21 CFR 866.5850
Regulation Name: Neurologic disease predisposition risk assessment system
Regulatory Class: Class II
Product Code: SFC
Dated: June 18, 2024
Received: June 21, 2024

Dear Huseyin Firat:

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 APO-Easy Genotyping kit, a prescription device with the following indications for use:

> The APO-Easy Genotyping kit is a qualitative polymerase chain reaction (PCR) test intended for the detection of two single nucleotide polymorphisms (SNPs), rs429358 and rs7412, in the APOE gene using genomic DNA extracted from human EDTA whole blood. The APOE genotype information provided by the test is used with other laboratory and clinical information to aid in the evaluation of the risk of developing late-onset Alzheimer's Disease (AD) in patients presenting with cognitive impairment and/or with predisposing risk factors, who are being evaluated for AD and other causes of cognitive decline.
>
> The APO-Easy Genotyping kit is not a screening or diagnostic test and does not determine the person's overall risk of developing late-onset AD. It is not intended to replace any clinical and diagnostic examinations.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the APO-Easy Genotyping kit, and substantially equivalent devices of this generic type, into Class II under the generic name neurologic disease predisposition risk assessment system.

FDA identifies this generic type of device as:

Neurologic disease predisposition risk assessment system. A neurologic disease predisposition risk assessment system is a prescription in vitro diagnostic device intended to detect or measure DNA**,** RNA, or protein variants in human specimens. The measurements aid in the evaluation of the risk of developing a neurologic disease in patients presenting with symptoms and/or with disease-associated risk factors to aid in patient management, in conjunction with other laboratory and clinical information.

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 21, 2024, FDA received your De Novo requesting classification of the APO-Easy Genotyping kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the APO-Easy Genotyping kit 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 APO-Easy Genotyping kit 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 leading to false positive or false negative results.	Design verification and validation, including certain analytical and clinical studies. Certain labeling information, including limiting statements.
Inappropriate interpretation of test results.	Design verification and validation, including certain analytical and clinical studies. Certain labeling information, including limiting statements.

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

(1) Design verification and validation must include:

(i) Device performance data demonstrating appropriate analytical performance for the intended use specimen type(s), including precision and reproducibility, detection limit of the device, linearity, assay interference, cross-reactivity, specimen and reagent stability, and analytical accuracy studies, as determined to be appropriate by FDA. For devices that are intended to measure multiple genetic or protein variants, the performance data must demonstrate the analytical performance of the device for each individual variant and for any output(s) that combine multiple variants.

(ii) Clinical performance data or evidence to support the intended use of the device. The neurological disease risk assessment must be representative of the intended use population and include well-established scientific literature, clinical performance data, or both, as determined to be appropriate by FDA.

(2) The labeling must include:

(i) Limiting statements that the test is not a screening or diagnostic test and that the test does not determine the patient's overall risk of developing the specified neurologic disease.

(ii) An appropriate summary, as determined by FDA, of the performance data or evidence that relate to all design verification and validation special controls, as well as a description of the 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.

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 neurologic disease predisposition 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 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 Matthew Butcher at 1-301-796-0784.

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Deputy Director
Division of Immunology and Hematology Devices
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