(ii) Detailed descriptions of analytical performance including, as applicable, precision, reproducibility, accuracy, limits of detection, and interferences as specified in paragraph (b)(1)(i) of this section, in language appropriate for the intended user;

(iii) A warning statement that the patient should not use the test results to stop or change any medication, and that medications should always be taken as prescribed by a healthcare professional;

(iv) A limiting statement explaining that this test is not intended to inform the patient about their current state of health, including whether the patient should or should not take a medication, or how much of a medication the patient should take, as appropriate;

(v) A warning statement that the test does not diagnose any health conditions and is not a substitute for visits to a doctor or other healthcare professional; and

(vi) A prominent and conspicuous limiting statement that the test provides only a preliminary test result that needs to be confirmed using an independent pharmacogenetic test without such a limitation prior to making any medical decisions. Alternatively, appropriate design verification and validation activities, including the generation of robust analytical data demonstrating appropriate analytical accuracy and reliability of test results for each genetic variant included in the test report, must be performed that demonstrate that the test can be used to make well-informed clinical decisions.

(3) The test report must include an appropriate description of how the test results should be used by healthcare providers who may receive the test results from their patients, as applicable.

(4) Publicly available pre-purchase labeling with unrestricted access that contains the following information must be provided:

(i) A clear description of the test and its technology, the genotypes detected, and relevant clinical claims associated with each genotype;

(ii) A clear description of what information the test will provide. This includes variant information, the limitations associated with the test, and any precautionary information about the test the user should be aware of before purchase; and

(iii) A discussion of answers to frequently asked questions that is sufficient to provide intended users with an appropriate understanding of information specific to each pharmacogenetic association that is claimed.

(5) The genetic test must use a sample collection device that is FDA-cleared or -approved, or classified as 510(k) exempt, with an indication for in vitro diagnostic use in DNA testing.

(6) The intended use of the device must not include an indication for use in supporting or sustaining human life, being of substantial importance in preventing impairment of human health, or presenting a potential, unreasonable risk of illness or injury.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16037 Filed 8–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–2107]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Menopause Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the menopause test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the menopause test system. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective August 21, 2025. The classification was applicable on October 24, 2018.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the menopause test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person

determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 22, 2018, FDA received Ansh Labs LLC's request for De Novo classification of the picoAMH ELISA test. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on October 24, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.1093.[1] We have named the generic type of device ''menopause test system,'' and it is identified as in vitro diagnostic device intended to measure hormones or other analytes in human clinical specimens as an aid in the determination of menopausal status in women.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—MENOPAUSE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Incorrect test results	Special controls (1) and (2).
Incorrect interpretation of test results	Special controls (1) and (2).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 862.1093 to subpart B to read as follows:

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

§ 862.1093 Menopause test system.

(a) *Identification.* A menopause test system is an in vitro diagnostic device intended to measure hormones or other analytes in human clinical specimens as an aid in the determination of menopausal status in women.

(b) *Classification.* Class II (special controls). A menopause test system must comply with the following special controls:

(1) Design verification and validation must include the following:

(i) An appropriate traceability plan to minimize the risk of drift in the menopause test system results over time.

(ii) Detailed documentation of a clinical study to demonstrate clinical performance or, if appropriate, results from an equivalent sample set. This detailed documentation must include the following information:

(A) Results must demonstrate appropriate clinical performance relative to a well-accepted and appropriate comparator.

(B) Data must demonstrate accuracy of device output for each indicated specimen type throughout the device measuring range as appropriate for the intended use population.

(2) The labeling required under § 809.10 of this chapter must include the following:

(i) A statement in the indications for use that the device is intended to be used for the determination of menopausal status only in conjunction with other clinical and laboratory findings prior to any diagnostic or treatment decisions.

(ii) A limiting statement that the device is intended to be used for the determination of menopausal status only in conjunction with other clinical and laboratory findings prior to any diagnostic or treatment decisions.

(iii) A limiting statement appropriately describing the risks of false test results and that test results should not be relied upon in clinical decision making (*e.g.,* to discontinue contraceptive use and/or to evaluate patients for the presence of endometrial cancer) without other clinical and laboratory findings.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16036 Filed 8–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2025–N–2788]

Medical Devices; Immunology and Microbiology Devices; Classification of A Multiplex Respiratory Panel To Detect and Identify Emerging Respiratory Pathogen(s) and Common Respiratory Pathogens in Human Clinical Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the multiplex respiratory panel to detect and identify emerging respiratory pathogen(s) and common respiratory pathogens in human clinical specimens into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the multiplex respiratory panel to detect and identify emerging respiratory pathogen(s) and common respiratory pathogens in human clinical specimens. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective August 21, 2025. The classification was applicable on November 24, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the multiplex respiratory panel to detect and identify emerging respiratory pathogen(s) and common respiratory pathogens in human clinical specimens as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.