available as listed in the **ADDRESSES** section of this document.

The Rule

This action amends 14 CFR part 71 by modifying Class D and Class E airspace over Westfield, MA. This action updates the airport name in both the Westfield Class D and Class E airspace legal descriptions from ''Westfield, Barnes Municipal Airport'' to ''Westfield-Barnes Regional Airport.'' This action also updates the geographic coordinates of the Westfield-Barnes Regional Airport in both the Class D and Class E airspace legal descriptions, specifically, from (lat. 42°09′28″ N, long. 72°42′56″ W) to (lat. 42°09′29″ N, long. 72°42′57″ W), which is one second of latitude and one second of longitude. This action also updates the verbiage in the Class D airspace legal description from ''Airport/Facility Directory'' to ''Chart Supplement'' to comply with current FAA guidance. This action also removes the exclusions for the adjacent Class E airspace areas of Northampton, MA, Palmer, MA and Windsor Locks, CT from the Westfield, MA Class E5 airspace legal description in order to comply with current FAA guidance.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Order 2100.6B, ''Rulemaking and Guidance Procedure'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' paragraph B–2.5(a). This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANE MA D Westfield, MA [Amended]

Westfield-Barnes Regional Airport, MA
(Lat. 42°09′29″ N, long. 72°42′57″ W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 4.9-mile radius of Westfield-Barnes Regional Airport excluding that airspace within the Springfield/Chicopee, MA, Class D airspace area during the dates and times it is effective, and that airspace within the Windsor Locks, CT, Class C airspace area. This Class D airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

* * * * *

6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Westfield, MA [Amended]

Westfield-Barnes Regional Airport, MA
(Lat. 42°09′29″ N, long. 72°42′57″ W)

That airspace extending upward from 700 feet above the surface within a 12.8-mile radius of Westfield-Barnes Regional Airport.

* * * * *

Issued in College Park, Georgia, on July 22, 2026.

Patrick Young,

Acting Manager, Tactical Operations Team, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2026–15062 Filed 7–23–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2026–N–7658]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Prognostic Test for Assessment of Chronic Kidney Disease Progression

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the prognostic test for assessment of chronic kidney disease progression 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 prognostic test for assessment of chronic kidney disease progression. 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 July 24, 2026. The classification was applicable on June 29, 2023.

FOR FURTHER INFORMATION CONTACT: Adam Ruben, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3506, Silver Spring, MD 20993–0002, 240–402–1431, *Adam.Ruben@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the prognostic test for assessment of chronic kidney disease progression into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 classification 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 premarket notification (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 section 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 August 26, 2020, FDA received Renalytix AI, Inc.'s request for De Novo classification of the KidneyIntelX.dkd device. 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 of the device, 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 June 29, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 862.1223.[1] We have named the generic type of device ''prognostic test for assessment of chronic kidney disease progression,'' and it is identified as an in vitro diagnostic device intended to measure one or more analytes obtained from human samples as an aid in assessing the risk for progression of chronic kidney disease. This device is not intended for diagnosis of any disease, for serial monitoring of kidney disease progression, or for monitoring the effect of any therapeutic product.

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

[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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR PROGNOSTIC TESTS FOR ASSESSMENT OF CHRONIC KIDNEY DISEASE PROGRESSION

Identified risks to health	Mitigation measures
Incorrect performance of the device leading to false positive, false negative or failure to provide a result.	Certain design verification and validation activities and documentation. Certain labeling information, including certain limiting statements and performance characteristics.
Incorrect interpretation of test results	Certain design verification and validation activities and documentation. Certain labeling information, including certain limiting statements and performance characteristics.

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 of the device. 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.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for prognostic tests for assessment of chronic kidney disease progression. This device is therefore 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 normally 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 management 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 § 862.1223 to subpart B to read as follows:

§ 862.1223 Prognostic test for assessment of chronic kidney disease progression.

(a) *Identification.* A prognostic test for assessment of chronic kidney disease progression is an in vitro diagnostic device intended to measure one or more analytes obtained from human samples as an aid in assessing the risk for progression of chronic kidney disease. This device is not intended for diagnosis of any disease, for serial monitoring of kidney disease progression, or for monitoring the effect of any therapeutic product.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) Detailed documentation of a clinical study that includes the following:

(A) Information that demonstrates the clinical performance of the device in a population of patients with chronic kidney disease at the different reported risk categories for progression of their disease (*e.g.,* at lower risk, at increased risk) using samples from the intended use population collected from multiple intended sample collection sites, or through an alternative approach determined to be appropriate by FDA;

(B) Information that demonstrates the measured outcomes and the length of follow-up are clinically relevant to demonstrate the progression of the chronic kidney disease; and

(C) A description of subjects from the target population (*e.g.,* the severity of underlying disease) and any exclusion or inclusion criteria.

(ii) Detailed documentation of a reference interval study that includes:

(A) Data generated in samples from healthy individuals; and

(B) Estimation of the upper and lower limits of the reference intervals and percentages of healthy individuals in each device-identified risk category.

(iii) When appropriate, detailed information that demonstrates the precision of the numeric values of the device output (score) based on the precision profiles of each individual input.

(iv) When appropriate, detailed information on the impact of the cumulative effect of potential interferents on the numeric values of the device output (score) based on the information known or determined for the potential of interference for each individual input.

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

(i) Limiting statements indicating that:

(A) The test results are not intended to diagnose any disease or condition;

(B) The test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including information obtained by alternative methods, and clinical evaluation, as appropriate; and

(C) The device is not intended for serial monitoring of kidney disease progression or for monitoring the effect of any therapeutic product.

(ii) Limiting statements, where applicable, describing the limitations on the clinical interpretations of the test results.

(iii) Limiting statements, where applicable, describing the limitations to the data generated in the clinical study(ies).

(iv) Detailed information on device performance in relevant subgroups (*e.g.,* severity of chronic kidney disease determined at the beginning of the observation period in the clinical study).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14984 Filed 7–23–26; 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–2026–N–6733]

Medical Devices; Immunology and Microbiology Devices; Classification of the Over-the-Counter Test To Detect SARS-CoV-2 From Clinical Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the over-the-counter test to detect SARS-CoV–2 from 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 over-the-counter test to detect SARS-CoV-2 from 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 July 24, 2026. The classification was applicable on June 6, 2023.

FOR FURTHER INFORMATION CONTACT: John McManus, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3221, Silver Spring, MD 20993–0002, 240–402–7964, *John.McManus@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the over-the-counter test to detect SARS-CoV-2 from clinical specimens into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 classification 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 premarket notification (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 section 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 May 2, 2022, FDA received Cue Health Inc.'s request for De Novo classification of the Cue COVID–19 Molecular 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 of the device, 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