Issue 001, dated September 13, 2023; or Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024''.

(3) Where paragraph 1.2.1 of Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 001, dated September 13, 2023, specifies ''Airbus Canada specific Repair Engineering Order (REO) with an issue date later than December 31, 2022 have already been validated and therefore do not require an additional approved disposition'', and where paragraph 1.2.1 of Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024, specifies ''Airbus Canada specific Repair Engineering Orders (REO) with an issue date later than December 31, 2022 have already been validated and therefore do not require an additional approved disposition'', this AD requires replacing that text with ''Airbus Canada specific Repair Engineering Orders (REOs) with an issue date later than December 31, 2022, and Generic Repair Engineering Orders (GREOs) with an issue date later than September 22, 2022, have already been validated and therefore do not require an additional approved disposition''.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* AIR–520, Continued Operational Safety Branch, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the AIR–520, Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or Transport Canada; or Airbus Canada Limited Partnership's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact Stefanie Roesli, Aviation Safety Engineer, FAA, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: *Stefanie.N.Roesli@faa.gov*.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following material was approved for IBR on May 27, 2025 (90 FR 16791, April 22, 2025).

(i) Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 001, dated September 13, 2023.

(ii) Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024.

(iii) Transport Canada AD CF–2023–70, dated October 5, 2023.

(4) For Airbus Canada material identified in this AD, contact Airbus Canada Limited Partnership, 13100 Henri-Fabre Boulevard, Mirabel, Québec J7N 3C6, Canada; telephone 450–476–7676; email a220_ website *a220world.airbus.com*.

(5) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation*.

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on May 23, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–09769 Filed 5–27–25; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–1281]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Anti-Mullerian Hormone Test System

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 anti-mullerian hormone 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 the anti-mullerian hormone test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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 May 30, 2025. The classification was applicable on December 19, 2016.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the anti-mullerian hormone 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 (see 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 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 December 14, 2015, FDA received Roche Diagnostics' request for De Novo classification of the Elecsys AMH system. 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 21 U.S.C. 360c(a)(1)(B)). 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 general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2016, FDA issued an order to the requestor classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 862.1092.[1] We have named the generic type of device anti-mullerian hormone test system, and it is identified as an in vitro diagnostic device intended to measure anti-mullerian hormone in human serum and plasma. An anti-mullerian hormone test system is intended to be used as an aid for assessing ovarian reserve 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—ANTI-MULLERIAN HORMONE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Inaccurate test results that provide false positive results may lead to a modification, delay or cancellation before a controlled ovarian stimulation procedure is initiated.	General controls and special controls (1) (21 CFR 862.1092(b)(1)) and (2) (21 CFR 862.1092(b)(2)).
Inaccurate test results that provide false negative results that may lead to the development of ovarian hyperstimulation syndrome in patients incorrectly thought to have normal and/or diminished ovarian reserve.	General controls and special controls (1) (21 CFR 862.1092(b)(1)) and (2) (21 CFR 862.1092(b)(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 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. 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

[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.

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 § 862.1092 to subpart B to read as follows:

§ 862.1092 Anti-mullerian hormone test system.

(a) *Identification.* An anti-mullerian hormone test system is an in vitro diagnostic device intended to measure anti-mullerian hormone in human serum and plasma. An anti-mullerian hormone test system is intended to be used for assessing ovarian reserve in women.

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

(1) Design verification and validation must include:

(i) An adequate traceability plan to minimize the risk of drift in anti-mullerian hormone test system results over time.

(ii) Detailed documentation of a prospective 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 adequate clinical performance relative to a well-accepted comparator.

(B) Clinical sample results must demonstrate consistency of device output throughout the device measuring range that is appropriate for the intended use population.

(C) Clinical study documentation must include the original study protocol (including predefined statistical analysis plan), study report documenting support for the proposed indications for use(s), and results of all statistical analyses.

(iii) Reference intervals generated by testing an adequate number of samples from apparently healthy normal individuals in the intended use population.

(2) The labeling required under § 809.10(b) of this chapter must include a warning statement that the device is intended to be used for assessing the ovarian reserve in conjunction with other clinical and laboratory findings before starting any fertility therapy, and that the device should be used in conjunction with the antral follicle count.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09776 Filed 5–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 230

[FHWA Docket No. FHWA–2019–0026]

RIN 2125–AF87

State Highway Agency Equal Employment Opportunity Programs

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FHWA is removing outdated and duplicative regulations requiring State highway agencies to submit to FHWA, on an annual basis, Equal Employment Opportunity (EEO) Program plans for FHWA approval. Currently, FHWA is responsible for oversight of State highway agencies' EEO programs, which include collection and analysis of internal employment data, development of an internal affirmative action hiring plan, and contractor compliance reporting. These regulations overlap with, and are duplicative of, other Federal requirements enforced by other Federal agencies. In addition, an Executive order (E.O.) issued by President Donald J. Trump repealed a previous E.O. that was relied on to initially promulgate the regulation. Elimination of these regulations will reduce administrative and monetary burdens on Federal-aid recipients.

DATES: This final rule is effective June 30, 2025.

FOR FURTHER INFORMATION CONTACT: Nichole McWhorter, Acting Associate Administrator, Office of Civil Rights, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–1396, *Nichole.McWhorter@dot.gov;* or James Esselman, Office of the Chief Counsel, Federal Highway Administration, 1200 New Jersey Avenue SE, Room E82–322, Washington, DC 20590, (202) 366–6181, *James.Esselman@dot.gov.* Office hours are from 8 a.m. to 4:30 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, as well as the notice of proposed rulemaking (NPRM) and all comments received, may be viewed online through the Federal eRulemaking portal at *www.regulations.gov.* The website is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's website at: *www.federalregister.gov* and the Government Publishing Office's website at: *www.GovInfo.gov.*

Background

On November 30, 2020, at 85 FR 76500, FHWA published a notice of proposed rulemaking (NPRM) proposing to remove its State Highway Administration Equal Employment Opportunity Programs regulations at 23 Code of Federal Regulations (CFR) part 230, subpart C. These regulations require State highway agencies to submit to FHWA, on an annual basis, EEO Program plans, which include collection and analysis of internal employment data, development of an internal affirmative action hiring plan, and contractor compliance reporting. The NPRM described how these regulations overlap with, and are duplicative of, other Federal requirements ensuring nondiscrimination in employment that are enforced by other Federal agencies. The NPRM further outlined how elimination of FHWA's regulations would reduce administrative and monetary burdens on FHWA recipients.

The FHWA received four public comment submissions in response to the NPRM. Commenters included two State highway agencies and two individuals. One of the individuals supported the proposed rule. The second individual's comments did not address the NPRM at all. One State highway agency did not express an opinion in favor of or against the proposed regulatory rescission, but commented that it was not concerned by the duplicative nature of FHWA's EEO regulations, noting that while other authorities require the submission of data, no other authorities require the submission of EEO program plans. The second State highway agency