

PART 232—REGULATION S—T— GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78n–1, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

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■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: “General Information,” Version 43 (March 2026). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 78 (September 2026). All EDGAR material referenced in this paragraph is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is made available for inspection by the Commission and the National Archives and Records Administration (NARA). The EDGAR Filer Manual may be obtained from the SEC’s website at <https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual>. For information on the availability of the EDGAR Filer Manual at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

By the Commission.

Dated: September 14, 2026.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026–20461 Filed 10–5–26; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2026–N–4268]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Certain Clinical Toxicology Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order setting forth its final determination to exempt certain class II clinical toxicology test systems from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k) requirements, subject to certain limitations, is immediately in effect for such devices. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is amending the classification language within the Code of Federal Regulations (CFR) for certain class II clinical toxicology test systems to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective October 6, 2026.

FOR FURTHER INFORMATION CONTACT:

Joseph Kotarek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3528, Silver Spring, MD 20993, 301–796–2718, Joseph.Kotarek@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and FDA’s implementing regulations in part 807, subpart E of the CFR (21 CFR part 807, subpart E), persons who are required to register and who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a 510(k) to FDA. The device may not be marketed until FDA (we or the Agency) finds it “substantially equivalent” within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not

require premarket approval. A 510(k) is not required for devices in certain situations, such as when they have been exempted from that requirement under section 510(m) of the FD&C Act.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. After providing at least a 60-day public comment period, FDA must then publish in the **Federal Register** a list representing the final determination with respect to the devices contained in the list under section 510(m)(1)(B) of the FD&C Act. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon FDA’s own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and provide a 60-day period for public comment.

Exemptions from premarket notification for certain clinical toxicology test systems, in addition to exemptions for other device types, were proposed and finalized in 2017. FDA published its initial notice for these clinical toxicology test systems under section 510(m)(1)(A) of the FD&C Act in the **Federal Register** of March 14, 2017 (82 FR 13609), and issued its final determination of exemption of the devices in a notice in accordance with section 510(m)(1)(B) of the FD&C Act in the **Federal Register** of July 11, 2017 (82 FR 31976). In the **Federal Register** of December 30, 2019 (84 FR 71794), FDA amended the relevant sections of the CFR to reflect the exemptions finalized in July 2017.

In the **Federal Register** of May 1, 2026 (91 FR 23427) (“the May 2026 notice”), FDA published a notice announcing its intent to expand the exemptions from premarket notification requirements for certain class II clinical toxicology test systems to additional devices within the device types and provided 60 days for interested persons to submit comments

by June 30, 2026. Specifically, FDA announced its intent to remove the exception for devices intended for Federal drug testing programs from the 510(k) exemptions for the clinical toxicology test systems identified in the May 2026 notice. FDA received comments from approximately 70 commenters during the 60-day comment period. FDA's responses to the timely received comments can be found in section III of this order. This final order sets forth our final determination to expand the exemptions for the class II clinical toxicology test systems that were the subject of the May 2026 notice. Through this action, FDA is amending the language for the identified classification regulations (21 CFR 862.3100(b), 862.3150(b), 862.3170(b), 862.3250(b), 862.3270(b), 862.3580(b), 862.3610(b), 862.3620(b), 862.3630(b), 862.3640(b), 862.3650(b), 862.3700(b), 862.3870(b), and 862.3910(b)) to reflect this final determination.¹

This final order is expected to result in decreased regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. Specifically, regulated industry will no longer have to invest time and resources in 510(k) submissions for devices exempt from such requirements.

II. Factors FDA Generally Considers for Exemption

There are a number of factors FDA generally considers to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, titled "Procedures for Class II Device Exemptions from Premarket Notification" (Ref. 1).

Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary or if an exemption would be appropriate for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2)

characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices from 510(k) requirements, these devices would still be subject to general limitations of exemptions. FDA's determinations that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness for class II devices are often based on the Agency's knowledge of the devices, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption, as discussed in section IV of this notice.

III. Comments on the Proposed Exemptions and FDA's Response

In the May 2026 notice, FDA announced its intent to expand the 510(k) exemptions for certain class II clinical toxicology test systems to additional devices within the device types, subject to certain limitations, upon its own initiative, and provided opportunity for interested persons to submit comments by June 30, 2026. After reviewing the comments received, FDA is now providing its final determination on expanding the 510(k) exemptions for the class II clinical toxicology test systems listed in table 1 to include devices intended for use in Federal drug testing programs, subject to certain limitations as identified in this order. FDA is also amending the codified language for the classification regulations for the class II clinical toxicology test systems listed in table 1 to reflect this final determination.

In response to the May 2026 notice announcing FDA's intent to expand the 510(k) exemptions for certain class II clinical toxicology test systems, FDA received comments from approximately 70 commenters, including individuals, trade organizations, regulated industry, labor unions, and other interested parties. Some of the comments contained one or more comments on one or more issues.

The order of the comments and our response to them is purely for organizational purposes and does not signify the comment's value or

importance or the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar. Please note that in some cases we separated different issues discussed by the same commenter and designated them as distinct comments for purposes of our responses.

(Comment 1) The majority of commenters expressed support for the proposed expansion of the 510(k) exemptions. Commenters stated that they believed the proposal, if finalized, would reduce unnecessary regulatory burdens. Commenters noted that device manufacturers would no longer need to invest time and resources into 510(k) submissions for newly exempt test systems. Many commenters stated that there would be no drop-off in the quality or accuracy of test systems used in Federal drug testing programs should the exemptions be finalized, and one commenter added that unnecessary barriers to adoption of clinical toxicology test systems in Federal drug testing programs are a public safety concern. Several commenters described the proposal as "a practical, overdue, and well-reasoned step toward a federal drug testing framework that reflects current science and operational reality."

(Response 1) FDA agrees with the commenters' support for the expansion of the 510(k) exemptions. In this order, FDA is finalizing the proposed exemptions without modification.

(Comment 2) Some commenters requested clarification regarding the scope of the proposed expanded 510(k) exemptions included in the May 2026 notice. Specifically, commenters asked whether a test system would be exempted from 510(k) requirements by the exemptions proposed in the May 2026 notice when the test system measures a different analyte, uses a different methodology, or has a different cutoff concentration than all already cleared devices in a generic device type included in the May 2026 notice. Another commenter asked FDA to clarify that a "Federal-program-specific predicate is not required for an eligible test system to fall within the exemption." Many comments encouraged FDA to liberally interpret the boundaries of the finalized exemptions.

(Response 2) FDA encourages commenters to review the finalized partial limitations of exemption discussed in section IV of this order as well as § 862.9 (21 CFR 862.9) (titled "Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act)"). Under § 862.9(a), a device that otherwise

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.

would fall within a 510(k) exemption is not exempt from 510(k) requirements when “[t]he device is intended for a use different from the intended use of a legally marketed device in that generic type of device.” As reflected in table 1, a test system must be intended for employment and insurance testing to fall within the 510(k) exemptions for the generic device types that are the subject of this order. Additionally, under § 862.9(b), such a device is not exempt from 510(k) requirements when the “device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device.” These general limitations of exemption apply to generic device types exempted from 510(k) requirements by this order as well as other generic device types classified in 21 CFR part 862.

Whether a specific test system is or is not exempt from 510(k) requirements depends on the specifics of the test system. FDA encourages manufacturers who have questions about whether a specific test system is exempt from 510(k) requirements to discuss their test system with FDA. Manufacturers may consider submitting a request for information under section 513(g) of the FD&C Act (21 U.S.C. 360c(g)). For more information regarding section 513(g) of the FD&C Act requests for information, please see FDA’s guidance document titled “FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal, Food, Drug, and Cosmetic Act” (Ref. 2).

(Comment 3) Multiple commenters requested that FDA clarify its authority around Federal drug testing programs and how this authority interacts with that of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Laboratory Certification Program (NLCP). Other commenters requested that FDA, SAMHSA, and the NLCP coordinate to reduce regulatory requirements.

(Response 3) FDA’s Center for Devices and Radiological Health aims to assure that patients and providers have safe, effective, and high-quality medical devices and safe radiation-emitting products. The term “device” is defined under section 201(h) of the FD&C Act (21 U.S.C. 321(h)) to mean, in relevant part, “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— . . . (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . and which does not

achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”

FDA does not administer or implement Federal drug testing programs. However, FDA regulates test systems used in Federal drug testing programs. Manufacturers and importers of devices such as clinical toxicology test systems may be subject to a variety of requirements under the FD&C Act and FDA’s regulations, including establishment registration, device listing, 510(k), labeling, quality management system, and medical device reporting requirements. Class II devices that are 510(k) exempt are still subject to other applicable requirements.

SAMHSA’s Division of Workplace Programs oversees Federal drug-free workplace programs, which aim to eliminate illicit drug use in Federal workplaces. It also oversees the NLCP, which certifies laboratories to conduct forensic drug testing for Federal agencies and federally regulated industries. SAMHSA has published mandatory guidelines for drug testing for urine (88 FR 70768) and for oral fluid (88 FR 70814).

FDA agrees that FDA, SAMHSA, and the NLCP should coordinate to best protect the public health, which may include reducing regulatory requirements where appropriate. In this final order, FDA is expanding the 510(k) exemptions for certain clinical toxicology test systems to include devices intended for Federal drug testing programs. Upon publication of this order, a 510(k) will no longer be required for such devices (subject to the general limitations of exemption under § 862.9 and the partial limitations of exemption identified in table 1).

(Comment 4) Two commenters stated that test systems used for Federal drug testing programs are not devices because they do not meet the definition of a device in the FD&C Act, and therefore, these test systems are not subject to FDA regulation.

(Response 4) FDA disagrees. As previously discussed in our response to comment 3, as defined in section 201(h) of the FD&C Act, the term “device” means, in relevant part, “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— . . . (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of

disease, in man or other animals . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” Drugs of abuse test systems, even when used for employment and insurance testing, are intended to provide information about a condition, namely, whether drugs of abuse are being used or have been used by the subject (see 65 FR 18230 at 18232). Therefore, the test systems newly exempted in this order are devices.

(Comment 5) Some commenters stated that the May 2026 notice did not specify what standards would replace 510(k) requirements for the test systems newly exempted by this order.

(Response 5) For clinical toxicology test systems that are newly exempted in this order, FDA has determined that a 510(k) is not necessary to assure the safety and effectiveness of the device, in accordance with section 510(m)(2) of the FD&C Act. Clinical toxicology test systems of the types listed in table 1 are therefore exempt from 510(k) requirements, including when such test systems are intended for use in Federal drug testing programs, upon publication of this order, subject to the general limitations of exemption under § 862.9 and the partial limitations of exemption identified in table 1. No standards or additional requirements replace 510(k) requirements for these devices. However, as discussed in our response to comment 3, 510(k) exempt devices remain subject to other applicable regulatory requirements, including SAMHSA’s mandatory guidelines, to the extent they are used in Federal drug testing programs.

(Comment 6) Many commenters stated that finalizing the expansion of the 510(k) exemptions proposed in the May 2026 notice is a necessary step for the implementation of oral fluid testing in Federal drug testing programs, including those programs administered by SAMHSA and the Department of Transportation (DOT). Some comments questioned why, or expressed frustration that, oral fluid testing has not yet been “approved” for use in these programs. Other commenters stated that delays in implementing oral fluid testing in Federal drug testing programs have had, and will continue to have, effects on transportation safety.

(Response 6) FDA is expanding the 510(k) exemptions for the clinical toxicology test systems identified in table 1 of this order because, in consideration of the factors listed in section II of this order, FDA has

determined that a 510(k) is not necessary to assure the safety and effectiveness of these devices, subject to the general limitations of exemption under § 862.9 and the partial limitations of exemption identified in table 1. While FDA understands that the expansion of the exemptions finalized in this order may facilitate the use of oral fluid testing in Federal drug testing programs, FDA does not oversee Federal drug testing programs (as noted in our response to comment 3) and so does not decide whether oral fluid testing may be used in such programs.

(Comment 7) Some commenters stated that finalizing the expansion of the 510(k) exemptions proposed in the May 2026 notice is a necessary step for the implementation of hair testing in Federal drug testing programs, including those programs administered by SAMHSA and DOT.

(Response 7) As noted in our response to comment 3, FDA does not oversee Federal drug testing programs and so does not decide whether hair testing may be used in such programs. Please see our response to comment 6.

(Comment 8) Multiple commenters stated that in addition to the 510(k) exemptions proposed in the May 2026 notice, FDA should exempt additional device types from 510(k) requirements, including test systems for phencyclidine (PCP); all class II clinical toxicology test systems intended for employment or insurance testing; all test systems used in Federal drug testing programs, including automatic additions when new drugs are added to Federal drug testing programs; unspecified additional test systems not intended for employment and insurance testing; and oral fluid collection devices.

(Response 8) These comments are outside the scope of what was proposed in the May 2026 notice and are, therefore, outside the scope of this final order. FDA notes that the 510(k) exemptions in this order are being finalized under the authority of section 510(m)(2) of the FD&C Act, which allows FDA to exempt only class II devices from 510(k) requirements, yet some of the additional device types suggested by comments have not been classified into class II. In addition, some of the device types suggested by the comments have different safety and effectiveness profiles (*e.g.*, oral fluid collection devices) than the test systems for which 510(k) exemptions are being finalized in this order. FDA has not made a determination that a 510(k) is not necessary to assure the safety and effectiveness of oral fluid collection devices; thus, finalizing a 510(k) exemption for them would not be

appropriate. FDA notes that there are 510(k)-cleared oral fluid collection devices that may be used with test systems for any drug of abuse analyte.

As indicated in table 1, the list of device types for which FDA is expanding 510(k) exemptions in this order is unchanged from the list proposed in the May 2026 notice.

(Comment 9) One commenter requested clarification regarding product code DJG being listed in the non-exempt product codes in the May 2026 notice and whether fentanyl test systems under product code DJG are exempt from 510(k) requirements if they are intended solely for employment and insurance testing. A different commenter requested clarification regarding whether fentanyl test systems are included in this order because fentanyl test systems were not mentioned by name in the May 2026 notice.

(Response 9) While fentanyl test systems and test systems for other opioids were not mentioned by name in the May 2026 notice, such test systems generally fall within the classification regulation for opiate test systems (§ 862.3650), which is one of the generic device types for which FDA is expanding the 510(k) exemptions in this order. Under § 862.3650(a), an opiate test system is a device intended to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. Section 862.3650(a) also defines an opiate as any natural or synthetic drug that has morphine-like pharmacological actions. Test systems intended to test for fentanyl generally fall under this regulation. Therefore, fentanyl test systems intended for Federal drug testing programs are included in the 510(k) exemptions finalized in this order.

Test systems that previously were designated under product code DJG will now fall under product code PVH and are 510(k) exempt if they do not exceed the limitations of exemption discussed in section IV of this order, including the limitation that the test system be intended for use solely in employment or insurance testing. For each product code listed in the “Non-Exempt Product Codes” column of table 1 of this order, there is a corresponding product code under the “Exempt Product Code” column in the same row. When a device in the generic device type does not exceed the limitations of exemption discussed in section IV of this order, then that device is 510(k) exempt and falls under the corresponding exempt product code.

(Comment 10) One comment stated that the 510(k) exemption for opiate test systems (exempt product code PVH) should not include test systems for fentanyl and its analogs. This commenter implied that it is uniquely difficult to accurately test for fentanyl and its analogs compared to other drugs of abuse, and therefore, fentanyl test systems are not appropriate for 510(k) exemption.

(Response 10) FDA disagrees. FDA's classification of opiate test systems includes test systems intended to test for fentanyl (see our response to Comment 9), and FDA has previously exempted opiate test systems, including test systems intended to test for fentanyl, from 510(k) requirements subject to certain limitations. FDA does not believe that fentanyl test systems raise unique considerations above and beyond those that apply to other test systems in this order. In consideration of the factors which FDA generally considers to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device (see section II of this order), FDA has determined to expand the 510(k) exemption that already exists for opiate test systems (including test systems intended to test for fentanyl) to include test systems intended for Federal drug testing programs.

(Comment 11) Some commenters requested additional specificity regarding the labeling language needed to avoid exceeding the partial limitations of exemption applicable to all exemptions in this order, which state that the exemptions are limited to tests “for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.”

(Response 11) FDA does not believe it is necessary or appropriate to provide further specificity regarding the labeling statement identified in the partial limitations of exemption for the clinical toxicology test systems covered by this order. The commenters did not explain why they thought clarification of this statement was necessary or how the partial limitation as proposed in the May 2026 notice was unclear. A partial limitation of exemption indicates that FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for devices that exceed the limitation. Regarding the labeling statement at issue, FDA has determined that premarket notification is necessary if the labeling for the device does not indicate that the device is intended solely for employment and insurance testing, but FDA has not determined

that specific verbiage must be used for that statement. We therefore decline to provide additional specificity regarding the labeling statement identified in the partial limitations of exemption for these devices.

(Comment 12) Some commenters requested that FDA exercise enforcement discretion regarding compliance with labeling requirements for test systems that were previously 510(k) exempt for employment and insurance testing, and that are labeled as not intended for use in Federal drug testing programs, when now intended for use in Federal drug testing programs consistent with the expanded 510(k) exemptions finalized by this order.

(Response 12) FDA declines to adopt a general enforcement discretion policy as requested by these commenters. FDA expects the clinical toxicology test systems covered by this order, whether exempt from 510(k) requirements or not, to be labeled in accordance with all applicable labeling requirements under the FD&C Act and 21 CFR parts 801 and 809, including that the labeling not be false or misleading.

(Comment 13) Multiple commenters requested that FDA exercise enforcement discretion regarding 510(k) requirements for any test system used in Federal drug testing programs and subject to NLCP requirements, even when such test systems have not been exempted from 510(k) requirements. Many of these commenters also requested that FDA “stop regulating” devices intended for use in Federal drug testing programs and “transfer” any FDA authority over Federal drug testing programs to NLCP. In contrast, at least one commenter recommended that if FDA were “to stop regulating” test systems intended for use in Federal drug testing programs, FDA should not transfer its responsibilities to NLCP.

(Response 13) FDA declines to adopt a general enforcement discretion policy for 510(k) requirements for all test systems used in Federal drug testing programs. FDA is expanding the exemptions from 510(k) requirements for clinical toxicology test systems identified in this order to include test systems intended for use in Federal drug testing programs based on a determination that a 510(k) is not necessary to assure the safety and effectiveness of these devices (subject to the general limitations of exemption under § 862.9 and the partial limitations of exemption identified in table 1). To the extent these comments are requesting or recommending that jurisdiction over these tests systems be transferred from FDA to another Federal agency, such comments are outside the

scope of this final order and would require statutory changes by Congress. In addition, FDA considers aspects of these comments to arise from a mistaken premise that FDA oversees Federal drug testing programs and can transfer that authority to another agency. That is not the case. As noted in response 3, FDA regulates devices used in Federal drug testing programs but does not oversee Federal drug testing programs themselves.

(Comment 14) Some commenters stated their belief that if the expansion of the exemptions proposed in the May 2026 notice is finalized, the quality of test systems could decrease, including worse accuracy and reliability, because the devices will no longer undergo premarket review. One commenter suggested expanding the exemptions could lead to decreased confidence in the accuracy of Federal drug testing. Other commenters opposed the expansion of the 510(k) exemptions because the commenters believed expanding the exemptions could lead to increased medical device fraud.

(Response 14) FDA disagrees that the quality of test systems available for Federal drug testing programs will decrease due to the expansion of the exemptions from 510(k) requirements finalized in this order or that fraudulent devices will enter the market because of the expansion of the exemptions. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II clinical toxicology test systems subject to the limitations outlined in table 1. While 510(k) exempt test systems intended for use in Federal drug testing programs generally will no longer be subject to FDA premarket review requirements, they remain subject to other requirements under the FD&C Act and FDA’s regulations as discussed in our response to comment 3, including quality management system requirements, medical device reporting requirements, and labeling requirements. In addition, laboratories that test samples for Federal drug testing programs are subject to requirements associated with Federal drug testing programs and overseen by SAMHSA, including the mandatory guidelines. These requirements may allow interested parties to remain confident in the accuracy of Federal drug testing programs.

(Comment 15) Some commenters did not support the expansion of the 510(k) exemptions proposed in the May 2026 notice because they believed that the expansion could lead to increased highway safety incidents, including increased crashes, injuries, and/or loss

of life. The commenters believed that without premarket review, new exempt test systems that are not currently on the market may fail to correctly detect positive samples that would be detected by test systems currently used in Federal drug testing programs. Commenters also expressed similar concerns about other industries subject to DOT testing, including aviation, rail, transit, and maritime industries.

(Response 15) FDA disagrees with comments that suggest that expanding the 510(k) exemptions to include test systems intended for use in Federal drug testing programs will likely cause harm by leading to an increased frequency of highway crashes or other mishaps caused by impaired/intoxicated workers. These comments appear to be premised on the belief that once premarket review of certain test systems intended for use in Federal drug testing programs is no longer required, the test systems will less accurately detect positive samples. However, as noted in our response to comment 14, we disagree with that premise, including because other applicable requirements will help to ensure the safety and effectiveness of these test systems and the accuracy of testing conducted under Federal drug testing programs. In addition to the controls imposed by SAMHSA as discussed in response 14, applicable requirements under the FD&C Act and FDA regulations besides premarket review requirements will continue to apply to the test systems being made 510(k) exempt in this order. For example, manufacturers of test systems exempted from 510(k) requirements by this order remain subject to establishment registration, device listing, quality management system, and device labeling requirements, among other requirements and as applicable (see generally 21 CFR parts 801, 803, 807, 809, and 820). FDA therefore does not believe this order will result in newly exempted test systems lacking reasonable effectiveness in detecting positive samples.

(Comment 16) One commenter stated that they were opposed to the expansion of the 510(k) exemptions proposed in the May 2026 notice because, in their view, FDA caused injury in other contexts by lifting restrictions on medications, and they believed that expansion of the exemptions could similarly cause injury.

(Response 16) We are not clear as to what actions or events the commenter was referencing when stating that FDA has “gotten people killed or severely sick” by lifting restrictions on medications. Nevertheless, FDA disagrees that expanding the 510(k)

exemptions for the clinical toxicology test systems identified in this order to include when such test systems are intended for use in Federal drug testing programs is likely to cause harm to patients. The expansion of the exemptions only applies to test systems that are intended for employment and insurance testing. While these test systems are intended to provide information about a condition, namely, whether drugs of abuse are being used or have been used by the subject, these test systems are not intended to be used to make treatment decisions. Therefore, FDA does not agree that the expansion of the exemptions finalized in this order is likely to cause harm to patients.

(Comment 17) A few commenters stated that finalizing the expansion of the exemptions proposed in the May 2026 notice could cause potential disruption to existing Federal drug testing programs or unintended compliance challenges for interested parties in the drug testing industry.

(Response 17) FDA disagrees with these comments. Tests systems intended for use in Federal drug testing programs that were previously authorized by FDA can continue to be used in such programs (assuming compliance with other applicable laws). The final order will enable additional test systems intended for Federal drug testing programs to be legally marketed without first obtaining 510(k) clearance from FDA. Therefore, FDA does not agree that finalization of this order could cause disruption to existing Federal drug testing programs.

(Comment 18) One commenter alleged that non-Federal workplace drug testing programs are often poorly run, and that the expansion of the 510(k) exemptions for the clinical toxicology test systems identified in this order, to include such test systems when intended for use in Federal drug testing programs, would open Federal drug testing programs to poor management seen in these other programs.

(Response 18) FDA does not agree that the finalization of the exemptions in this order will likely affect the management quality of Federal drug testing programs. This order exempts certain clinical toxicology test systems intended for use in Federal drug testing programs from FDA's 510(k) requirements but does not otherwise affect Federal drug testing programs, including the management thereof. FDA believes that the only effect this order will have on Federal drug testing programs is the possible increase in the number of test systems that may be utilized in such programs.

(Comment 19) Some commenters urged FDA to finalize the expansion of the exemptions proposed in the May 2026 notice as soon as possible.

(Response 19) FDA agrees with the commenters that the expansion of the exemptions proposed in the May 2026 notice should be finalized. The comment period regarding the expansion of the exemptions proposed in the May 2026 notice closed on June 30, 2026. FDA has worked to finalize this order as soon as was practicable following consideration of the comments submitted on the May 2026 notice.

(Comment 20) One commenter requested that FDA open a docket regarding how it assigns product codes for "[F]ederally mandated workplace drug test system devices." This commenter indicated that an analyte-specific categorization framework may be inconsistent with modern drug testing systems which generally rely on multi-analyte platforms.

(Response 20) As explained in FDA's guidance document titled "Medical Device Classification Product Codes" (the Product Codes guidance), "[c]lassification product codes are a method of internally classifying and tracking medical devices" (Ref. 3). The Product Codes guidance states that product codes are assigned and maintained by the Agency, and are used to, among other things, "help to delineate technology and indication subgroups within a regulation." FDA currently does not intend to open a docket regarding product code assignment. However, as stated in the Product Codes guidance, "[a]s technology changes and 510(k) review practice evolves, some classification product codes may become obsolete. In some cases, product code definitions may be updated to accommodate new technology." As technology continues to evolve, FDA may consider modifications to the product codes assigned to the clinical toxicology test systems covered in this order.

(Comment 21) Various comments expressed displeasure with the commenters' personal circumstances connected to failed (or invalid) drug tests administered as part of a Federal drug testing program and/or displeasure with how SAMHSA, the NLCP, the DOT, and other non-FDA organizations administer and/or regulate Federal drug testing programs. Many of these comments were addressed to entities other than FDA. These comments did not address the expansion of the exemptions proposed in the May 2026 notice.

(Response 21) These comments are outside the scope of the May 2026 notice and this order. As discussed in more detail in comment 3, FDA does not oversee Federal drug testing programs.

IV. Limitations of Exemptions

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II clinical toxicology test systems subject to the limitations outlined in table 1. This determination is based, in part, on the Agency's knowledge of the devices, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

The exemptions from premarket notification requirements for the class II device types listed in table 1 apply only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostics, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality (see § 862.9). Thus, a manufacturer of a device listed in this order will still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into interstate commerce for commercial distribution when the device exceeds any of the limitations of exemptions described in § 862.9.

B. Partial Limitations of Exemptions

In addition to the general limitations described in section IV.A of this notice, partial limitations may limit an exemption from premarket notification requirements to specific devices within a device type. In such situations where a partial limitation of the exemption has been identified, FDA has determined that premarket notification is necessary to assure the safety and effectiveness for devices that exceed the limitations.

Prior to issuance of this order, the classification regulations listed in table 1 already included an exemption from 510(k) requirements (subject to the general limitations in § 862.9 as discussed in section IV.A of this notice) "provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing," and as long as the device was not intended for use in Federal drug testing

programs.² In this order, FDA is removing the exception to the 510(k) exemption for devices intended for Federal drug testing programs. As such, devices in the device types listed in table 1 are exempt from 510(k) requirements even if intended for use in Federal drug testing programs as long as they do not exceed any of the general limitations of exemptions in § 862.9, and provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, as described in table 1.

When FDA finalized the partial exemptions from 510(k) requirements

that were in effect for the classification regulations listed in table 1 prior to issuance of this order, FDA assigned new product codes to ensure that exempt and non-exempt devices within a device type would have separate product codes (82 FR 31976 at 31977). FDA will continue to use the previously established product codes; however, the definitions of the product codes for exempt devices will be modified to accurately reflect the scope of the exemption,³ and devices which are newly exempt will change from a non-exempt product code to the corresponding exempt product code.

V. List of Class II Devices

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of clinical toxicology test systems of the types listed in table 1 when they are intended for Federal drug testing programs (see “New Partial Limitations” listed in table 1). Devices in the device types listed in table 1 no longer require premarket notification under section 510(k) of the FD&C Act when they are intended for Federal drug testing programs, so long as they do not exceed the partial limitations of exemptions specified in table 1 and the corresponding general limitations of exemptions found in § 862.9.

TABLE 1—CLASS II DEVICES

21 CFR section	Generic device type	Exempt product code	Non-exempt product codes	Partial limitations prior to issuance of this order	New partial limitations
862.3100	Amphetamine test system.	PUX	DIT, DJL, DJP, DKZ, DNI, DOD, DPJ, NFT, NVI, OIW.	Exemption is limited to test systems intended to measure amphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure amphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3150	Barbiturate test system.	PUY	DIS, DJN, DKN, DKX, DLX, DMF, KZY, PTH.	Exemption is limited to test systems intended to measure barbiturates for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure barbiturates for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3170	Benzodiazepine test system.	PUZ	JXM, KZZ, LAA, LAB, NFV.	Exemption is limited to test systems intended to measure any of the benzodiazepine compounds for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the benzodiazepine compounds for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3250	Cocaine and cocaine metabolite test system.	PVA	DIN, DIO, DIR, DLN, DMN, DNG, DOM, JXO, KLN, LAC, NFY.	Exemption is limited to test systems intended to measure cocaine and a cocaine metabolite (benzoylecgonine) for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure cocaine and a cocaine metabolite (benzoylecgonine) for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3270	Codeine test system.	PVB	DLD, LAD, LAE	Exemption is limited to test systems intended to measure codeine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure codeine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3580	Lysergic acid diethylamide (LSD) test system.	PVC	DLB, DOL	Exemption is limited to test systems intended to measure LSD for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure LSD for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.

² 21 CFR 862.3100, 862.3150, 862.3170, 862.3250, 862.3270, 862.3580, 862.3610, 862.3620, 862.3630, 862.3640, 862.3650, 862.3700, 862.3870, and 862.3910; 84 FR 71794. Federal drug testing programs include, for example, programs run by the Substance Abuse and Mental Health Services

Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.

³ For example, prior to issuance of this order, the definition for product code PUX (Test, Amphetamine, Employment and Insurance Testing, Exempt) included a reference to 82 FR 31976 (the

action establishing the exemption). Following publication of this order, this reference, and corresponding ones for the other 510(k)-exempt product codes, will be replaced with a reference to this order which codifies the expanded scope of the exemption.

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Generic device type	Exempt product code	Non-exempt product codes	Partial limitations prior to issuance of this order	New partial limitations
862.3610	Methamphetamine test system.	PVD	DJC, LAF, LAG, NGG.	Exemption is limited to test systems intended to measure methamphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methamphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3620	Methadone test system.	PVE	DIW, DJR, DKR, DMB, DNT, DPP, PTG.	Exemption is limited to test systems intended to measure methadone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methadone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3630	Methaqualone test system.	PVF	KXS	Exemption is limited to test systems intended to measure methaqualone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methaqualone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3640	Morphine test system.	PVG	DIQ, DJJ, DLR, DMY, DNA, DNK, DOE, DOK, DPK, NGI.	Exemption is limited to test systems intended to measure morphine and its analogs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure morphine and its analogs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3650	Opiate test system	PVH	DJF, DJG, DKT, DLT, LAH, LAI, NGL.	Exemption is limited to test systems intended to measure any of the addictive narcotic pain-relieving opiate drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the addictive narcotic pain-relieving opiate drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3700	Propoxyphene test system.	PVI	DPN, JXN, LAJ, LAK, QBF.	Exemption is limited to test systems intended to measure propoxyphene for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure propoxyphene for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3870	Cannabinoid test system.	PVJ	DKE, LAT, LDJ, NFW.	Exemption is limited to test systems intended to measure any of the cannabinoids for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the cannabinoids for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3910	Tricyclic antidepressant drugs test system.	PVK	LFG, LFH, LFI, MLK, QAW.	Exemption is limited to test systems intended to measure any of the tricyclic antidepressant drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the tricyclic antidepressant drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) 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.

VII. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of

information. This final order refers to previously approved collections of information. 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 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, the collections of

information in 21 CFR parts 801 and 809, regarding device labeling, have been approved under OMB control number 0910–0485, and the collections of information in 21 CFR part 820, regarding quality management system regulation, have been approved under OMB control number 0910–0073.

VIII. References

The following references are on display at the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA Guidance, "Procedures for Class II Device Exemptions from Premarket Notification," February 19, 1998, available at <https://www.fda.gov/media/72685/download>.
2. FDA Guidance, "FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal, Food, Drug, and Cosmetic Act," August 23, 2024, available at <https://www.fda.gov/media/78456/download>.
3. FDA Guidance, "Medical Device Classification Product Codes," April 11, 2013, available at <https://www.fda.gov/media/82781/download>.

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. In § 862.3100, revise paragraph (b) to read as follows:

§ 862.3100 Amphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). An amphetamine test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 3. In § 862.3150, revise paragraph (b) to read as follows:

§ 862.3150 Barbiturate test system.

* * * * *

(b) *Classification.* Class II (special controls). A barbiturate test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 4. In § 862.3170, revise paragraph (b) to read as follows:

§ 862.3170 Benzodiazepine test system.

* * * * *

(b) *Classification.* Class II (special controls). A benzodiazepine test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 5. In § 862.3250, revise paragraph (b) to read as follows:

§ 862.3250 Cocaine and cocaine metabolite test system.

* * * * *

(b) *Classification.* Class II (special controls). A cocaine and cocaine metabolite test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 6. In § 862.3270, revise paragraph (b) to read as follows:

§ 862.3270 Codeine test system.

* * * * *

(b) *Classification.* Class II (special controls). A codeine test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 7. In § 862.3580, revise paragraph (b) to read as follows:

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

* * * * *

(b) *Classification.* Class II (special controls). A lysergic acid diethylamide (LSD) test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 8. In § 862.3610, revise paragraph (b) to read as follows:

§ 862.3610 Methamphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). A methamphetamine test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 9. In § 862.3620, revise paragraph (b) to read as follows:

§ 862.3620 Methadone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methadone test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

- 10. In § 862.3630, revise paragraph (b) to read as follows:

§ 862.3630 Methaqualone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methaqualone test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and

includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

■ 11. In § 862.3640, revise paragraph (b) to read as follows:

§ 862.3640 Morphine test system.

* * * * *

(b) *Classification.* Class II (special controls). A morphine test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

■ 12. In § 862.3650, revise paragraph (b) to read as follows:

§ 862.3650 Opiate test system.

* * * * *

(b) *Classification.* Class II (special controls). An opiate test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

■ 13. In § 862.3700, revise paragraph (b) to read as follows:

§ 862.3700 Propoxyphene test system.

* * * * *

(b) *Classification.* Class II (special controls). A propoxyphene test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

■ 14. In § 862.3870, revise paragraph (b) to read as follows:

§ 862.3870 Cannabinoid test system.

* * * * *

(b) *Classification.* Class II (special controls). A cannabinoid test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter

subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

■ 15. In § 862.3910, revise paragraph (b) to read as follows:

§ 862.3910 Tricyclic antidepressant drugs test system.

* * * * *

(b) *Classification.* Class II (special controls). A tricyclic antidepressant drugs test system is not exempt if it is intended for any use other than employment or insurance testing. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20448 Filed 10–5–26; 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–10990]

Medical Devices; Immunology and Microbiology Devices; Classification of the High Throughput DNA Sequencing for Hereditary Cancer Predisposition Assessment Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the high throughput DNA sequencing for hereditary cancer predisposition assessment 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 high throughput DNA sequencing for hereditary cancer predisposition assessment test system. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 October 6, 2026. The classification was applicable on September 29, 2023.

FOR FURTHER INFORMATION CONTACT:

Jingya Wang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3250, Silver Spring, MD 20993–0002, 301–837–7257, Jingya.Wang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the high throughput DNA sequencing for hereditary cancer predisposition assessment test system into class II (special controls), which we have determined will provide a reasonable assurance of the 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