

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.

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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

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 March 29, 2021, FDA received Invitae Corporation’s request for De Novo classification of the Invitae Common Hereditary Cancers Panel. 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 the 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 September 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 866.6095.¹ We have named the generic type of device “high throughput DNA sequencing for hereditary cancer predisposition assessment test system,” and it is identified as a qualitative in vitro diagnostic (IVD) system intended for analysis of human DNA extracted from human specimens to detect germline mutations in a panel of targeted cancer-related genes. It is intended to aid in hereditary cancer predisposition assessment by qualified health care professionals in accordance with professional guidelines. The device is not intended for screening, prenatal testing, or as a stand-alone diagnostic test. The device is for prescription use only.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR HIGH THROUGHPUT DNA SEQUENCING FOR HEREDITARY CANCER PREDISPOSITION ASSESSMENT TEST SYSTEMS

Identified risks to health	Mitigation measures
False positive, false negative, or failure to provide a result.	Certain design verification and validation including certain analytical and clinical studies, and mutation annotation and clinical interpretation rules identified in special control (1). Certain labeling information including limitations, device descriptions, methodology and protocols, and performance information identified in special control (2).
Incorrect interpretation of variants/alterations by the lab.	Certain design verification and validation including certain analytical and clinical studies, and mutation annotation and clinical interpretation rules identified in special control (1). Certain labeling information including limitations, device descriptions, methodology and protocols, and performance information identified in special control (2).
Incorrect interpretation of test results by the healthcare provider.	Certain design verification and validation including certain analytical and clinical studies, and mutation annotation and clinical interpretation rules identified in special control (1). Certain labeling information including limitations, device descriptions, methodology and protocols, and performance information identified in special control (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 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.

At the time of classification, high throughput DNA sequencing for hereditary cancer predisposition assessment test systems are for prescription use only. Therefore, these devices are subject to the prescription

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.

labeling requirements for IVD products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

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 high throughput DNA sequencing for hereditary cancer predisposition assessment test systems. 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 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.6095 to subpart G to read as follows:

§ 866.6095 High throughput DNA sequencing for hereditary cancer predisposition assessment test system.

(a) *Identification.* A high throughput DNA sequencing for hereditary cancer predisposition assessment test system is a qualitative in vitro diagnostic (IVD) system intended for analysis of human DNA extracted from human specimens to detect germline mutations in a panel of targeted cancer-related genes. It is intended to aid in hereditary cancer predisposition assessment by qualified health care professionals in accordance with professional guidelines. The device is not intended for screening, prenatal testing, or as a stand-alone diagnostic test. The device is for prescription use only.

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

(1) Design verification and validation must include:

(i) A description of genomic coverage that includes:

(A) A list of all genes, variant types, and target regions within each gene that the device detects;

(B) Summary information regarding the clinical significance of each gene, including references;

(C) A description of the genes with high clinical significance that are detected by the device, defined as genes for which the test result(s) may lead to prophylactic screening, confirmatory procedures, or treatment that may incur morbidity or mortality; and

(D) A description of any within-gene targeted regions that cannot be reported.

(ii) Specifications for specimen requirements, including any specimen collection devices, handling, and storage.

(iii) Specifications of the DNA extraction method and criteria for DNA quality and quantity that are prerequisite to performing the assay.

(iv) Detailed documentation of the methodology and protocols for each step of the test, including reagents, instrumentation, and software required. The documentation must include the analysis algorithms used for mutation detection and annotation, and specify the quality metrics, variant calling thresholds, and filters at each step of the test, including the criteria for run

failures, batch failures, specimen failures, invalid calls (e.g., failed quality control), and “no calls” (i.e., absence of a result), as applicable.

(v) Description of required instrumentation and equipment, and any ancillary reagents, instrumentation, or equipment.

(vi) Detailed documentation of device software, including software applications and hardware-based devices that incorporate software. The documentation must include verification, validation, hazard analysis, and risk assessment activities.

(vii) Documentation of internal and external controls that are recommended or provided and control procedures. The documentation must identify those control elements that are incorporated into the testing procedure.

(viii) Detailed documentation pertaining to the probability of test failure based on data from clinical samples, description of scenarios in which a test can fail, and any risk mitigations, including follow-up actions to be taken.

(ix) Detailed documentation of the rules, procedures, tools, and criteria used for establishing mutation-hereditary disease relationships and mutation annotation, evaluation, and classification (e.g., pathogenic, likely pathogenic, variant of unknown significance, benign, and likely benign).

(x) Detailed documentation of any internal or external database(s) or decision rules used for mutation annotation, including:

(A) The protocol(s) used for variant interpretation, including training of personnel, monitoring accuracy of decision, resolution of discordant interpretations, and updating interpretations;

(B) Detailed documentation of the basis for interpretation, including the use of alternate databases, literature, and guidelines, and the basis for risk reporting;

(C) Methods for data preservation and security; and

(D) Data formats and nomenclature.

(xi) Information that demonstrates the performance characteristics of the device, evaluated either specifically for each gene/mutation or, when determined to be acceptable and appropriate by FDA, using a representative approach based on other mutations of the same type, including:

(A) Data that adequately support the intended specimen type(s) (e.g., whole blood), specimen handling protocol, and DNA extraction method.

(B) A summary of the evidence that demonstrates how the analytical quality metrics and thresholds used to

determine the acceptability of reporting support the minimum accuracy requirements.

(C) Data to adequately support device accuracy using clinical specimens representing all indicated specimen types, mutation types, and size ranges intended to be detected and reported by the device. Accuracy data must fulfill the following:

(1) Accuracy of the device must be evaluated with clinical specimens collected in accordance with the device labeling and selected without bias, or well-characterized human cell line samples, when determined to be acceptable and appropriate by FDA.

(2) Accuracy must be evaluated by comparison to bidirectional Sanger sequencing or other orthogonal methods identified as appropriate by FDA. Performance criteria for both the comparator method(s) and the device must be predefined and appropriate to the device's intended use. Detailed study protocols must be documented.

(3) A sufficient number of specimens must be tested. For BRCA1 and BRCA2 genes, a minimum of 120 variant positive specimens must be tested. For other genes with high clinical significance, at least 40 variant-positive specimens must be tested per gene, including representative specimens for each indicated variant type based on a justification determined to be appropriate and acceptable by FDA. For remaining genes detected by the device, testing must include variant positive specimens representing each variant type, unless the variant type has a prevalence of less than 0.01 percent. Specimen selection must be prioritized based on clinical significance. The selected specimens must be representative of zygosity and challenging genomic context (e.g., guanine-cytosine content, near tandem repeats and homopolymer stretches, pseudogene), and must cover the range of sizes (for insertions, deletions, copy number variant (CNV) amplifications and CNV deletions) intended to be detected and reported by the device.

(4) Except as permitted by FDA under paragraph (b)(1)(xi)(C)(5) of this section, tested specimens must be selected based on results obtained from the orthogonal method. Positive percent agreement (PPA) and negative percent agreement (NPA) must be calculated and demonstrated for each variant type detected and reported by the device, as well as for clinically relevant variants. PPA is calculated as the number of variants that are tested positive by both the device and the orthogonal method (true "positives" (TP)) divided by the number of variants tested positive as

determined by the orthogonal method (TP plus false negatives (FN) by the device). NPA is calculated as the number of variants that are tested negative (wild type) by both the device and the orthogonal method (true "negatives" (TN)) divided by the number of variants tested negative (wild type) by the orthogonal method (TN plus false positives (FP) by the device). Point estimates for PPA and NPA must be calculated along with 95 percent two-sided confidence intervals (CI).

Uncertainty of the point estimate must be within an acceptable range, as identified by FDA, and must be demonstrated using the 95 percent CI.

(5) When it is determined by FDA to be appropriate and acceptable to select samples based on the results obtained with the device, accuracy must be presented as technical positive predictive value (TPPV) and technical negative predictive value (TNPV). TPPV relates to the likelihood that a variant call is a true positive and reflects the number of false positives per test. TPPV is calculated as the number of variants that are tested positive by both the device and the orthogonal method (TP) divided by the number of variants tested positive by the device (TP plus FP). TNPV relates to the likelihood that a variant call is a true negative and reflects the number of false negatives per test. TNPV is calculated as the number of variants that are tested negative by both the device and the orthogonal method (TN) divided by the number of variants tested negative by the device (TN plus FN).

(6) Any "no calls" or invalid calls in the study must be reported separately. The percent of final "no calls" or invalid calls must be clinically justifiable.

(7) Accuracy as a function of each performance metric (e.g., coverage depth, base quality scores) must be documented to provide evidence of the accuracy of the overall run.

(8) Detailed documentation for accuracy of the device must include information and results for the overall study, each mutation type, and each gene. The accuracy must further be described based upon stratification within each mutation type by zygosity, genomic context, and size (for indels and CNVs). Overall accuracy for reporting of substitutions must be ≥ 99.0 percent; insertions and deletions, ≥ 99.0 percent; CNVs, ≥ 99.0 percent for positive agreement (PPA, TPPV); and ≥ 99.9 percent for negative agreement (NPA, TNPV).

(D) Documentation of the data to adequately support device precision using clinical specimens representing

all specimen types, mutation types, and sizes intended to be detected and reported by the device. The precision study must fulfill the following:

(1) The study must be performed using multiple instruments and multiple operators, on multiple non-consecutive days, and using multiple reagent lots. If the device is to be performed at more than one site, different sites must be included and reproducibility across sites must be evaluated.

(2) Representative clinical specimens of each mutation type must be tested (both positive and negative), considering clinical significance, prevalence, zygosity, genomic context, and size (for indels and CNVs). The precision for CNV detection must be demonstrated on the gene level for genes with high clinical significance. Alternatively, a justification for why such data are not needed must be found acceptable and appropriate by FDA.

(3) The study must assess the performance of all steps, including DNA extraction, unless a separate extraction study is performed.

(4) The study must use predefined performance criteria. Agreement estimates such as PPA/NPA and average positive agreement/average negative agreement must be provided, including point estimates and 95 percent confidence intervals. Documentation from the precision study must be demonstrated for the overall precision study, in addition to each mutation type, each gene, and each sample. Precision must further be demonstrated upon stratification within each mutation type by zygosity, genomic context, and size (for indels and CNVs). The overall precision point estimates for each variant type must be >99.0 percent.

(5) Any "no calls" or invalid calls in the study must be included in precision study results and reported separately. The percent of "no calls" or invalid calls and key quality control metrics parameters (e.g., coverage, sequencing score) must be summarized and based on stratification in the same way as the precision estimates.

(E) Documentation of the nucleic acid assay input range and the evidence to adequately support the range.

(F) Detailed documentation of additional analytical validation studies, including endogenous and exogenous interfering substances, specimen and reagent stability, cross-reactivity, carryover and cross-contamination, guard-banding, and index misassignment, as applicable. If specimens are pooled, index cross-contamination must be evaluated and

demonstrate that pooling does not negatively impact test performance.

(G) Specimen type and matrix comparison data must be generated if more than one specimen type or anticoagulant can be tested with the device, including failure rates for the different specimen types.

(xii) Information that adequately supports the variant annotation and clinical interpretation of the test must include:

(A) A summary documenting the clinical significance for each gene on the test panel, including the associated conditions/cancers, the most prevalent and representative mutations, and summary of clinical evidence with references, including expected frequency in the general population and different ethnicities, and risks of developing the disease in relevant ethnic populations and the general population.

(B) Detailed documentation of the data to adequately support the performance of the variant annotation algorithms (e.g., concordance studies between the device generated variant classifications and externally established variant classifications, manual classifications by medical professionals, or classifications generated from clinical test reports).

(C) Documentation of any procedures or protocols for incorporation of any updates of valid scientific evidence into variant classification algorithms.

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

(i) The intended use must include a description of the intended specimen type(s) and matrix (e.g., whole blood), the validated germline mutation types (e.g., single nucleotide variant, insertion, deletion, CNV), and a statement that the test is for hereditary cancer predisposition assessment and to aid in identifying hereditary genetic variants potentially associated with a diagnosed cancer.

(ii) The name of the testing facility or facilities (e.g., for single-site assays).

(iii) A summary of device description in accordance with paragraphs (b)(1)(i) through (b)(1)(viii) of this section.

(iv) A section that provides summary information on how the test works, how to interpret the results of the test, and an explanation on the database(s) used for mutation annotation.

(v) A summary of the information that demonstrates the performance characteristics of the device as required under paragraph (b)(1)(xi) of this section.

(vi) The following limiting statements:

(A) A statement that the test is not intended for use as a stand-alone diagnostic to diagnose cancer or other health conditions, and is not intended for use for prenatal testing nor as a cancer screening test.

(B) A statement that the test is specifically designed for heritable germline mutations and is not appropriate for the detection of somatic mutations.

(C) A description of the intended test population.

(D) A statement that the risk of cancer or disease for an individual cannot be predicted.

(E) A statement that: test results should be interpreted in the context of clinical findings, family history, lifestyle, environment, and other factors; molecular testing may not detect all possible mutations leading to cancer predisposition; a negative result does not rule out the possibility that the individual has an unidentified variant leading to cancer; and for more information, physicians ordering the test may wish to consult with a clinical medical geneticist or genetic counselor.

(F) A statement that other factors, such as ethnicity, may affect whether the test results are relevant for a particular patient and may also affect how their genetic health results are interpreted.

(G) A statement describing the situations that a patient should not receive the test (e.g., a patient with bone marrow transplant).

(H) A statement describing the challenging genomic contexts that may have reduced performance, where results should be interpreted with care.

(I) A statement disclosing the genetic coverage of the test, including any gaps in coverage.

(J) Statements describing testing conditions that were identified to cause test failures (e.g., low specimen volume, poor DNA quality).

(vii) For variants detected and reported by the device under the category of “variants of uncertain significance” or equivalent designation, a limiting statement that the clinical significance has not been demonstrated with adequate clinical evidence in accordance with established guidelines (e.g., professional guidelines).

(viii) For variants detected and reported by the device under the category of “variants with evidence of clinical significance” or equivalent designation, reference(s) for physicians to access internal or external information concerning decision rules

or conclusions about the level of evidence for clinical significance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20443 Filed 10–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–10995]

Medical Devices; Cardiovascular Devices; Classification of the Hyperoxia Monitoring Device Adjunct to Pulse Oximetry

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hyperoxia monitoring device adjunct to pulse oximetry 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 hyperoxia monitoring device adjunct to pulse oximetry. 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 October 12, 2023.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the hyperoxia monitoring device adjunct to pulse oximetry 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