

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]

BILLING CODE 4164–01–P

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:

Annie Abraham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1264, Silver Spring, MD 20993–0002, 240–402–5219, Annie.Abraham@fda.hhs.gov.

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

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 December 21, 2020, FDA received Masimo Corporation’s request for De Novo classification of the ORi device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of 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 October 12, 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 870.2720.¹ We have named the generic type of device “hyperoxia monitoring device adjunct to pulse oximetry,” and it is identified as a device that monitors elevated hemoglobin oxygen saturation levels as an adjunct to arterial oxygen saturation monitoring.

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 HYPEROXIA MONITORING DEVICES ADJUNCT TO PULSE OXIMETRY

Identified risks to health	Mitigation measures
Inaccurate measurement of hyperoxia or hypoxia leading to escalation of unneeded therapy and false reassurance.	Clinical performance testing.
Incorrect or delayed treatment due to over-reliance on device output for clinical decision-making without using arterial blood gas values for confirmation.	Clinical performance testing; Human factors/usability testing; and Labeling.
Procedure delay or inaccuracy due to software failure or corruption in data transfer	Software verification, validation, and hazard analysis.
Patient or operator injury due to electrical hazards	Electrical safety testing; and Electromagnetic compatibility testing.
Adverse tissue reaction	Biocompatibility evaluation.
Inaccurate measurement or infection due to unclean surfaces	Reprocessing validation; and Labeling.

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.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for hyperoxia monitoring devices adjunct to pulse oximetry. 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 part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

- 1. The authority citation for part 870 continues to read as follows:

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

- 2. Add § 870.2720 to subpart C to read as follows:

§ 870.2720 Hyperoxia monitoring device adjunct to pulse oximetry.

(a) *Identification.* A hyperoxia monitoring device adjunct to pulse oximetry is a device that monitors elevated hemoglobin oxygen saturation levels as an adjunct to arterial oxygen saturation monitoring.

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

(1) Clinical performance testing under anticipated conditions of use must evaluate the accuracy of hyperoxia monitoring by the device and evaluate all adverse events.

(2) Human factors/usability testing must demonstrate that the user can correctly use the device, based solely on reading the instructions for use.

(3) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must validate the reprocessing instructions for the device, including demonstration of device performance after repeated cleaning and disinfection.

(6) Software verification, validation, and hazard analysis must be performed. Performance testing must demonstrate compatibility with pulse oximeter devices labeled to be compatible with the device.

(7) Labeling must include:

(i) Cleaning and disinfection instructions;

(ii) A summary of the clinical performance testing with the device;

(iii) A warning against over-reliance on device output without using arterial blood gas values for confirmation; and

(iv) Instructions to monitor oxygen delivery and patient clinical/

cardiovascular status when device output changes.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20441 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 878

[Docket No. FDA–2026–N–10992]

Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound System for Non-Thermal, Mechanical Tissue Ablation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the focused ultrasound system for non-thermal, mechanical tissue ablation 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 focused ultrasound system for non-thermal, mechanical tissue ablation. 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 6, 2023.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD 20993–0002, 301–796–6412, Cal.Rabang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the focused ultrasound system for non-thermal, mechanical tissue ablation 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