

(D) Therapeutic failure or success cannot be determined based on the assay results, since nucleic acids may persist following appropriate antimicrobial therapy.

(7) The outer box label required under § 809.10(a) of this chapter must include the following:

(i) A description of who may use the home collection kit and age of the intended users.

(ii) A list of the components included.

(iii) A list of the components required, but not provided (e.g., software applications needed to complete the process).

(iv) A statement that this is a home sample collection kit which requires shipping of the sample to a laboratory within the specified timeframe to receive results.

(v) A statement that anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines).

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026-20727 Filed 10-8-26; 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-10993]

#### Medical Devices; Cardiovascular Devices; Classification of the Infant Pulse Rate and Oxygen Saturation Monitor for Over-the-Counter Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the infant pulse rate and oxygen saturation monitor for over-the-counter use 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 infant pulse rate and oxygen saturation monitor for over-the-counter use. 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 9, 2026. The classification was applicable on November 8, 2023.

#### FOR FURTHER INFORMATION CONTACT:

Kimberly Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993-0002, 301-796-6017, [Kimberly.Crowley@fda.hhs.gov](mailto:Kimberly.Crowley@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA (the Agency or we) has classified the infant pulse rate and oxygen saturation monitor for over-the-counter use 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 14, 2022, FDA received Owlet Baby Care, Inc.'s request for De Novo classification of the Dream Sock 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 November 8, 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 870.2705.<sup>1</sup> We have named the generic type of device “infant pulse rate

and oxygen saturation monitor for over-the-counter use,” and it is identified as a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s). 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 INFANT PULSE RATE AND OXYGEN SATURATION MONITORS FOR OVER-THE-COUNTER USE

| Identified risks to health                                                                                            | Mitigation measures                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Poor quality incoming photoplethysmography signal resulting in failure to detect pulse rate and oxygen saturation.    | Clinical performance testing; Human factors testing; Electrical safety testing; Electromagnetic compatibility testing; and Labeling.                         |
| Misinterpretation and/or over-reliance on device output, leading to failure to seek treatment despite acute symptoms. | Human factors testing; and Labeling.                                                                                                                         |
| Adverse tissue reaction .....                                                                                         | Clinical performance testing; Biocompatibility evaluation; Human factors testing; and Labeling.                                                              |
| False positive leading to unnecessary medical procedures .....                                                        | Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Human factors testing; and Labeling. |
| False negative resulting in failure to detect high or low pulse rate event and/or low SpO2 level event.               | Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Human factors testing; and Labeling. |

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 infant pulse rate and oxygen saturation monitors for over-the-counter use. 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 § 870.2705 to subpart C to read as follows:

§ 870.2705 Infant pulse rate and oxygen saturation monitor for over-the-counter use.

(a) Identification. An infant pulse rate and oxygen saturation monitor for over-the-counter use is a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s).

<sup>1</sup> 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.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:

(i) Evaluation of the effect of confounding variables, like skin pigmentation, on performance;

(ii) Demonstration of the consistency of the output and representativeness of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment; and

(iii) Evaluation of all adverse events, including skin irritation.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include:

(i) Technical specifications of the software, including software algorithm(s) and its inputs and outputs; and

(ii) Specification of acceptable incoming sensor data quality control measures.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmography signal quality and validate any alarms.

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

(5) Performance testing must support the electrical safety and electromagnetic compatibility of the electrical components of the device.

(6) Human factors and usability testing must demonstrate the following:

(i) The caregiver can correctly use the device based solely on reading the device labeling; and

(ii) The caregiver can correctly interpret the device outputs and understand next steps to take based on the outputs.

(7) Labeling must include:

(i) Instructions for identifying the intended use population of the device,

including populations where the device should not be used, and conditions of monitoring;

(ii) A description of what the device measures and outputs to the caregiver, including instructions for the interpretation of results and appropriate actions;

(iii) Situations in which the device may not operate at an expected performance level; and

(iv) Instructions for cleaning the device and cleaning frequency.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–20726 Filed 10–8–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–1641]

#### Schedules of Controlled Substances: Placement of O-Desmethyltramadol in Schedule I; Correction

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Correcting amendment.

**SUMMARY:** On August 12, 2026, the Drug Enforcement Administration (DEA) published a temporary order placing *O*-desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, in schedule I of the Controlled Substances Act. DEA published this temporary order that specifically noted in the summary that the control of *O*-desmethyltramadol included its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, however

inadvertently omitted the correct language that should have been included. This document corrects that error, adding the correct language.

**DATES:** This correcting amendment is effective October 9, 2026, until August 12, 2028, and applicable beginning August 12, 2026.

**FOR FURTHER INFORMATION CONTACT:** Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

**SUPPLEMENTARY INFORMATION:** The placement of *O*-desmethyltramadol under schedule I was effective on August 12, 2026.<sup>1</sup> After publication of the temporary scheduling order, DEA inadvertently omitted the correct language that should have been included in 21 CFR part 1308. This document corrects the language in 21 CFR part 1308 to include the isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible of *O*-desmethyltramadol.

#### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA corrects 21 CFR part 1308 with the following correcting amendment:

#### PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, revise paragraph (h)(88) to read as follows:

#### § 1308.11 Schedule I.

\* \* \* \* \*

(h) \* \* \*

(88) *O*-desmethyltramadol, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol) .....

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<sup>1</sup> Schedules of Controlled Substances: Temporary Placement of *O*-desmethyltramadol in Schedule I, 91 FR 52013 (Aug. 12, 2026).