

III. Analysis of Environmental Impact

We have 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 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

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

■ 2. Add § 868.1985 to subpart B to read as follows:

§ 868.1985 Spinal imaging system for neuraxial procedures.

(a) *Identification.* A spinal imaging system for neuraxial procedures is a sensor and software system that is used to assist in identification of the interspinous space for neuraxial procedures.

(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 and must evaluate:

(i) Rate of neuraxial procedure success across the intended use population;

(ii) Procedure time;

(iii) Adverse events, including pain, bleeding, unintended dural puncture, and injury to other spinal structures; and

(iv) Comparison of performance to manual palpation or alternative method of determination of the target insertion site.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate the accuracy, repeatability, and resolution of imaging of the underlying anatomy representative of intended use populations.

(3) Human factors testing must demonstrate that the user can correctly use the device based solely on the directions for use.

(4) Software verification, validation, and hazard analysis must be performed. Validation testing must verify and validate proper image construction.

(5) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

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

(7) Performance testing must demonstrate the sterility of any device components intended to be labeled sterile.

(8) Labeling must include a warning that risks inherent to neuraxial procedures under standard of care conditions are still present with use of the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22181 Filed 10–29–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2026–N–12385]

Medical Devices; Anesthesiology Devices; Classification of the Over-the-Counter Device To Assess Risk of Sleep Apnea

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the over-the-counter device to assess risk of sleep apnea 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 over-the-counter device to assess risk of sleep apnea. 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 30, 2026. The classification was applicable on February 6, 2024.

FOR FURTHER INFORMATION CONTACT: Prakhya Singh, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1255, Silver Spring, MD 20993–0002, 301–796–6562, Prakhya.Singh@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the over-the-counter device to assess risk of sleep apnea 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 May 31, 2023, FDA received Samsung Electronics Co., Ltd’s request for De Novo classification of the Sleep Apnea Feature. 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 February 6, 2024, 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 868.2378.¹ We have named the generic type of device “over-the-counter device to assess risk of sleep apnea,” and it is identified as a device that is intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.

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 OVER-THE-COUNTER DEVICES TO ASSESS RISK OF SLEEP APNEA

Identified risks to health	Mitigation measures
False negative resulting in failure to assess risk of sleep apnea and delay of further evaluation or treatment.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
False positive resulting in additional unnecessary medical procedures ..	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Misinterpretation and/or overreliance on device output, leading to:	
• Failure to seek treatment despite sleep apnea symptoms.	
• Discontinuing or modifying treatment for sleep apnea.	Human factors testing; and Labeling.
Poor quality sensor data input to the device software function resulting in incorrect sleep apnea assessment.	Non-clinical performance testing Software verification, validation, and hazard analysis; and Human factors testing Labeling.
Electrical shock, burn, or interference with other devices (for device hardware components).	Electrical safety testing; Electromagnetic compatibility testing; 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 (16 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR OVER-THE-COUNTER DEVICES TO ASSESS RISK OF SLEEP APNEA—Continued

Identified risks to health	Mitigation measures
Adverse tissue reaction (for device hardware components)	Biocompatibility evaluation.

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 over-the-counter devices to assess risk of sleep apnea. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have 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 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

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

■ 2. Add § 868.2378 to subpart C to read as follows:

§ 868.2378 Over-the-counter device to assess risk of sleep apnea.

(a) *Identification.* An over-the-counter device to assess risk of sleep apnea is intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.

(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. This testing must fulfill the following:

(i) Testing must include a study population representative of the intended use population for the device, including subjects symptomatic and asymptomatic of sleep apnea. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must evaluate device performance across all applicable subgroups (e.g., age, sex, body mass index, skin tone).

(iv) The assessment must compare device performance with a clinical comparator device (e.g., polysomnography) to demonstrate the required accuracy and/or sensitivity and specificity of the output measure(s). Justification for the clinical comparator as ground truth must be provided.

(v) For devices with machine learning-based algorithms, the clinical validation must be completed using a dataset that is separate from the training dataset.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must demonstrate hardware compatibility and the ability of the device software and hardware to provide adequate input signal quality and handle noisy or missing data and poor signal quality.

(3) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of any device hardware components.

(4) Any device hardware components that are skin-contacting must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed. Software documentation must include:

(i) Full characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics, associated hardware specifications, and processing software; and

(iii) A description of all mitigations for failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

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

(i) The user can correctly use the device based solely on reading the directions for use; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

- (7) Labeling must include:
 - (i) A description of what the device measures and outputs to the user;
 - (ii) Hardware platform and operating system requirements;
 - (iii) The type of sensor data used, including specifications of compatible hardware used for data acquisition;
 - (iv) Warnings identifying sensor acquisition factors or subject conditions or characteristics that may impact measurement results;
 - (v) Information for interpretation of the measurements, including a statement that the device is not intended to replace traditional methods of diagnosis (e.g., polysomnography) nor intended to be used as an apnea monitor;
 - (vi) A summary of the clinical performance testing with the device, including both the device's overall performance as well as performance across all relevant subgroups.

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 878

[Docket No. FDA-2026-N-12213]

Medical Devices; General and Plastic Surgery Devices; Classification of the Software-Aided Adjunctive Diagnostic Device for Use by Physicians on Lesions Suspicious for Skin Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer 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 software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer. 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 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT:

Rudy Andriani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4540, Silver Spring, MD 20993-0002, 240-402-6030, Rudy.Andriani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer 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 February 2, 2023, FDA received DermaSensor Inc.'s request for De Novo classification of the DermaSensor 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