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 § 868.2250 to subpart C to read as follows:

§ 868.2250 Monitor for opioid induced impairment of oxygenation.

(a) *Identification.* A monitor for opioid induced impairment of oxygenation is a device that uses sensor hardware and software algorithms to detect desaturations of arterial oxygen saturation resulting from opioid overdose.

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

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

(i) Comparison to a clinically relevant reference method to demonstrate and support the accuracy and level of sensitivity and specificity for detection of opioid induced impairment of oxygenation;

(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;

(iii) Performance reported in clinically significant and distinct subpopulations and intended use environments;

(iv) For devices using algorithms based on machine learning, the clinical validation must be completed using a dataset that is separate from the training dataset; and

(v) Simulated use testing of hardware and sensors to characterize accuracy and precision across the intended use population.

(2) Software description, verification, and validation based on comprehensive hazard analysis must be performed. Software documentation must include:

(i) Full characterization of technical parameters of the software, including any algorithm(s);

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

(iii) Justification for the validity of the algorithm(s) (*e.g.,* clinical relevance/importance of decision threshold).

(3) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Performance testing of sensor hardware to characterize sensor accuracy and precision; and

(ii) Compatibility testing of sensors with other hardware and software components of the device.

(4) Usability assessment must be provided to demonstrate that intended device users can safely and correctly use the device.

(5) All components of the device that contact the skin must be demonstrated to be biocompatible.

(6) Performance testing must demonstrate the electromagnetic compatibility, wireless coexistence, electrical safety, thermal safety, and mechanical safety of any hardware components and sensors of the device.

(7) Labeling must include the following:

(i) A summary of the clinical validation data, including relevant characteristics of the included subpopulations and use environments in the clinical study, and performance metrics, including sensitivity, specificity, positive predictive value, and negative predictive value for each of the subpopulations, use environments, and opioid types;

(ii) Principles of sensor operation, including warnings for how to avoid interfering with sensor readings;

(iii) Information for preventing an overdose, recognizing signs of an overdose, and treating an overdose;

(iv) Warnings identifying that the device is not designed to differentiate between the target condition (*e.g.,* opioid-induced respiratory depression) and other conditions that may cause a false reading (*e.g.,* obstructive sleep apnea);

(v) Warnings against overreliance on the device; and

(vi) A warning regarding the need for supervised use with awareness of effective countermeasures (*e.g.,* naloxone) in case of an overdose.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13140 Filed 6–29–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2026–N–6711]

Medical Devices; General and Plastic Surgery Devices; Classification of the Skin Patch for Treatment of Hyperhidrosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the skin patch for treatment of hyperhidrosis 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 skin patch for treatment of hyperhidrosis. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of 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 June 30, 2026. The classification was applicable on April 7, 2023.

FOR FURTHER INFORMATION CONTACT: Rachana Visaria, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1218, Silver Spring, MD 20993–0002, 240–402–5628, *Rachana.Visaria@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the skin patch for treatment of hyperhidrosis into class II (special controls), which we have determined will provide a reasonable assurance of 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 3, 2021, FDA received Candesant Biomedical, Inc.'s request for De Novo classification of the N–SWEAT Patch. 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 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 April 7, 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 878.4425.[1] We have named the generic type of device ''skin patch for treatment of hyperhidrosis,'' and it is identified as a prescription topical patch that utilizes a chemical reaction to generate thermal energy in situ for treatment of hyperhidrosis.

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 SKIN PATCHES FOR TREATMENT OF HYPERHIDROSIS

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation; and Labeling.
Device failure/malfunction leading to tissue damage	Non-clinical performance testing; Shelf life testing; and Labeling.
Adverse tissue effects as a result of the chemical reaction	Thermal safety testing; Clinical performance testing; and Labeling.
Failure to identify correct population and condition	Labeling.
Compensatory hyperhidrosis or bromohydrosis	Labeling.

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

[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.

named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, skin patches for treatment of hyperhidrosis are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

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 skin patches for treatment of hyperhidrosis. 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 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4425 to subpart E to read as follows:

§ 878.4425 Skin patch for treatment of hyperhidrosis.

(a) *Identification.* A skin patch for treatment of hyperhidrosis is a prescription topical patch that utilizes a chemical reaction to generate thermal energy in situ for treatment of hyperhidrosis.

(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 evaluate:

(i) Reduction in hyperhidrosis using a validated measure;

(ii) All adverse events; and

(iii) Impact of residual chemical on the skin.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Thermal reactivity of the active device component(s);

(ii) The total energy and energy flux (energy per unit area) of the device that is available to induce heating based on calorimetry; and

(iii) Characterization of the distribution and homogeneity of the chemical(s) on and within the device.

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

(4) Performance testing must support the shelf life of the device by demonstrating device functionality and package integrity over the labeled shelf life.

(5) Patient and physician labeling must include:

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

(ii) A listing of known risks including local adverse events, systemic effects, and adverse changes in perspiration; and

(iii) Information about the known duration of effect.

(6) Physician labeling must also include:

(i) Instructions for safe disposal of the device; and

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13139 Filed 6–29–26; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans to prescribe the spreads component of the interest assumption under the asset allocation regulation for plans with valuation dates of July 31, 2026–October 30, 2026. These interest assumptions are used for valuing benefits under terminating single-employer plans and for other purposes.

DATES: Effective July 31, 2026.

FOR FURTHER INFORMATION CONTACT: Jose Singer-Freeman (*singer-freeman.jose@pbgc.gov*), Attorney, Legislative and Regulatory Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, 202–229–5432. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions—including an interest assumption—for valuing benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumption is also posted on PBGC's website (*www.pbgc.gov*).

PBGC uses the interest assumption in § 4044.54 to determine the present value of annuities in an involuntary or