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 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.1454 to subpart B to read as follows:

§ 882.1454 Prognostic assessment software of mild cognitive impairment.

(a) *Identification.* Prognostic assessment software of mild cognitive impairment is a prescription-only device that combines information from multiple clinical data sources to produce an output indicative of the likelihood that a patient diagnosed with mild cognitive impairment will progress to more severe forms of cognitive impairment, or will develop dementia, such as Alzheimer's disease dementia, within a specified period of time. This device is intended for adjunctive use and not intended as a stand-alone diagnostic or prognostic tool.

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

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended when used to analyze data from the intended patient population, unless FDA determines, based on the totality of the information provided for premarket review, that data from postmarket surveillance is not required.

(i) Data provided from paragraph (b)(1) of this section must demonstrate the accuracy, precision, and reproducibility of the device for predicting progression of patients with mild cognitive impairment to more severe forms of cognitive impairment or to dementia, such as Alzheimer's disease dementia, based on a clinically relevant reference standard for the diagnosis of such disease states or conditions. The test data set must include data acquired from a patient population that is representative of the intended patient population normally seen in clinical practice. The test data set must be independent from data used in training/development of the device.

(ii) Objective performance measures (*e.g.,* sensitivity, specificity, positive predictive value, negative predictive value) must be reported with relevant descriptive or developmental performance measures.

(2) Software verification, validation, and hazard analysis must be provided. Software documentation must include a detailed, technical description of the model/algorithm(s) and algorithm inputs and outputs.

(3) Human factors/usability assessment must demonstrate that the intended user(s) in the intended use environment can correctly use the device and interpret the device output(s).

(4) Physician labeling must include:

(i) A detailed summary of the clinical performance testing methods, including results of the performance testing for tested performance measures/metrics, selection criteria, and the patient demographics;

(ii) A description of the patient population that was used in development or training of the device algorithm/model;

(iii) Device limitations or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) A statement that the device is not a stand-alone diagnostic or prognostic tool and that the device output should only be interpreted in the context of all available clinical information, including patient history, medications, and comorbidities; and

(v) Information for interpretation of the device outputs detailing the risks associated with misinterpretation of the device outputs.

(5) Patient labeling must include information explaining the device output(s) and the associated risks if the device output is incorrect.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22590 Filed 11–4–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2026–N–12211]

Medical Devices; Orthopedic Devices; Classification of the Wearable Vibration Device for Orthopedic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the wearable vibration device for orthopedic 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 wearable vibration device for orthopedic 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 November 5, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jesse Muir, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4462, Silver Spring, MD 20993–0002, 240–402–6679, *Jesse.Muir@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the wearable vibration device for orthopedic 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 February 17, 2023, FDA received Bone Health Technologies, Inc.'s request for De Novo classification of the Osteoboost Belt. 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 January 12, 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 888.5895.[1] We have named the generic type of device ''wearable vibration device for orthopedic use,'' and it is identified as a wearable device that uses mechanical vibrations, targeted to specific regions of the skeleton, to reduce loss of bone strength or bone mineral density.

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 WEARABLE VIBRATION DEVICES FOR ORTHOPEDIC USE

Identified risks to health	Mitigation measures
Accelerated loss of bone strength and bone mineral density resulting from application of inappropriate magnitude and/or frequency of vibration.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Electromagnetic compatibility testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Patient injury due to electrical, mechanical, or thermal hazards	Electrical safety testing; Electromagnetic compatibility testing; Mechanical and thermal safety testing; Software verification, validation, and hazard analysis; and Labeling.
Adverse effects on the patient, including regional pain, dizziness, blurred vision, muscle weakness, difficulty with balance, headache, and nausea.	Clinical performance testing; and Labeling.
User error leading to ineffective reduction in loss of bone strength or bone mineral density.	Clinical performance testing; Human factors/usability evaluation; 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 wearable vibration devices for orthopedic use. 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 888

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 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.5895 to subpart E to read as follows:

§ 888.5895 Wearable vibration device for orthopedic use.

(a) *Identification.* A wearable vibration device for orthopedic use is a wearable device that uses mechanical vibrations, targeted to specific regions of the skeleton, to reduce loss of bone strength or bone mineral density.

(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 evaluate the reduction in loss of bone strength or bone mineral density. Testing must evaluate patient risks, including regional pain, dizziness, blurred vision, muscle weakness, difficulty with balance, headache, and nausea. The testing must include a minimum of 1 year of follow-up.

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

(i) Characterization of the designed outputs of the device;

(ii) Demonstration of the reliability and reproducibility of device output; and

(iii) Validation that vibration characteristics received by the patient are within safe physiologic limits.

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

(4) Performance data must be provided to demonstrate the electrical safety, mechanical safety, thermal safety, battery safety, and electromagnetic compatibility of the device.

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

(6) Human factors or usability evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.

(7) Labeling must include the following:

(i) A summary of the clinical performance testing with the device, including clinical outcomes and observed adverse events;

(ii) Information regarding limitations of the clinical significance of the clinical performance testing;

(iii) Instructions on duration and frequency of use, and when to discontinue use of the device; and

(iv) Instructions for device maintenance, including appropriate cleaning of any reusable components and safe disposal of the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22589 Filed 11–4–26; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2026–1684; FRL–13268–02–R9]

Air Plan Revisions; Arizona; Maricopa County Air Quality Department; New Source Review; Emission Reduction Credits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is taking final action to approve a revision to the Maricopa County Air Quality Department (MCAQD or ''Department'') portion of the Arizona State Implementation Plan (SIP). This revision establishes a federally enforceable program allowing for the generation of emission reduction credits (ERCs) by retrofitting or replacing existing on-road vehicles with lower emitting vehicles while meeting other Clean Air Act (CAA or ''Act'') requirements. These ERCs are intended to be used as offsets for major stationary sources under the Department's Nonattainment New Source Review (NNSR) program. The EPA is approving this SIP revision because we find that it meets the applicable CAA requirements.

DATES: This rule is effective December 7, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2026–1684. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.