(i) Alternative Methods of Compliance (AMOCs)

The Manager, AIR–770, West Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the West Certification Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(j) Related Information

(1) For more information about this AD, contact David Kim, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: 562–627–5274; email: *David.Kim@faa.gov.*

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) of this AD.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Goodrich Service Bulletin 2057–25–075, Revision C, dated June 20, 2025.

(ii) Goodrich Service Bulletin 2071–25–046, Revision G, dated August 22, 2025.

(iii) Goodrich Service Bulletin 2157–25–092, Revision E, dated June 20, 2025.

(iv) Goodrich Service Bulletin 2201–25–013, Revision F, dated June 20, 2025.

Note 1 to paragraph (k)(2): This service information is also identified as the property of UTC Aerospace Systems and Collins Aerospace.

(3) For Goodrich material identified in this AD, contact Goodrich Aircraft Interior Products, 1275 North Newport Road, Colorado Springs, CO 80916–2779; phone: 719–380–0391; email: *cos_techpubs31218@collins.com;* website: *collinsaerospace.com.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on May 21, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–10806 Filed 5–28–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2026–N–5197]

Medical Devices; Neurological Devices; Classification of the Transcutaneous Electrical Nerve Stimulator To Treat Fibromyalgia Symptoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms 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 transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms. 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 May 29, 2026. The classification was applicable on May 18, 2022.

FOR FURTHER INFORMATION CONTACT: Chun Xu, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4256, Silver Spring, MD 20993–0002, *Chun.Xu@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms 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 October 5, 2021, FDA received NeuroMetrix, Inc.'s request for De Novo classification of the Quell-FM 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 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 May 18, 2022, 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 882.5888.[1] We have named the generic type of device ''transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms,'' and it is identified as a prescription device that transcutaneously stimulates a patient's sensory nerves through electrodes placed on the skin to treat fibromyalgia symptoms.

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 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR TO TREAT FIBROMYALGIA SYMPTOMS

Identified risks to health	Mitigation measures
Adverse tissue reaction.	Biocompatibility evaluation.
Skin discomfort, burns, electrical shock, or pain at stimulation site.	Electromagnetic compatibility testing; Electrical, mechanical, and thermal safety testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Device failure due to interference with other devices.	Electromagnetic compatibility testing; Software verification, validation, and hazard analysis; and Labeling.
Delayed or ineffective treatment due to user error.	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 named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, transcutaneous electrical nerve stimulators to treat fibromyalgia symptoms 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 transcutaneous electrical nerve stimulators to treat fibromyalgia symptoms. 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 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 § 882.5888 to subpart F to read as follows:

[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.

§ 882.5888 Transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms.

(a) *Identification.* A transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms is a prescription device that transcutaneously stimulates a patient's sensory nerves through electrodes placed on the skin to treat fibromyalgia symptoms.

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:

(i) Characterization of the electrical stimulation parameters, including the following: waveforms; output modes; maximum output voltage and maximum output current (at 500Ω, 2kΩ, and 10kΩ loads); pulse duration; frequency; net charge per pulse; maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500Ω);

(ii) Characterization of the impedance monitoring system; and

(iii) Characterization of electrode performance, including the electrical performance, adhesive integrity, shelf life, reusability, and current distribution of the electrode surface area.

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

(3) Performance testing must demonstrate electrical, thermal, and mechanical safety along with electromagnetic compatibility of the device in the intended use environment.

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

(5) Labeling must include the following:

(i) Recommended treatment regimes, including but not limited to, frequency and duration of use, application site(s), and typical sensations experienced during treatment;

(ii) A shelf life for the electrode and reuse information;

(iii) Summaries of the electrical stimulation parameters and device technical parameters (including any wireless specifications); and

(iv) Instructions on how to correctly use and maintain the device, including all user-interface components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10675 Filed 5–28–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SATS No. MT–048–FOR; Docket No. OSM–2025–0008; S1D1S SS08011000 SX064A000 266S180110; S2D2S SS08011000 SX064A000 26XS501520]

Montana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is APPROVING an amendment to the Montana regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Montana submitted this proposed amendment to OSM on its own initiative in response to a State law passed by the Montana Legislature House Bill 587 (HB 587). The proposed amendment provides a new definition of ''Material damage'' with respect to the hydrologic balance, alluvial valley floors, and subsidence. It also creates an option for a permit applicant to provide self-collected information related to its determination of probable hydrologic consequences, if an appropriate Federal or State agency cannot provide such information. Finally, HB 587 includes contingencies that apply to the proposed amendment but are not codified into the Montana Code Annotated (MCA): a severability clause, a contingent voidness clause, an effective date clause, and a retroactive applicability clause.

DATES: The effective date is June 29, 2026.

FOR FURTHER INFORMATION CONTACT:

Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Program

Section 503(a) of SMCRA permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with SMCRA and consistent with the Federal implementing regulations. *See* 30 U.S.C. 1253(a)(1) and (7); 30 CFR 730.5 and 732.15(a). On the basis of these criteria, the Secretary of the Interior conditionally approved the Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Montana program in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions concerning the Montana program and program amendments at 30 CFR 926.15.

II. Submission of the Amendment

By letter dated May 15, 2025 (Administrative Record No. MT–048–01), Montana sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). We found Montana's proposed amendment to be administratively complete on May 15, 2025. Montana submitted the proposed amendment to us, on its own volition, after the Montana legislature passed HB 587 during the 2025 legislative session. HB 587 amends the Montana Strip and Underground Mine Reclamation Act (MSUMRA) as well as sections 82–4–203 and 222 of the MCA.

Specifically, Montana proposes changes to its definition of ''Material damage,'' at 82–4–203(35) of the MCA. Montana proposes to remove the previous definition and create three sub-definitions. The first, paragraph (a), defines ''Material damage . . . with respect to the hydrologic balance outside the permit area,'' as a quantifiable adverse impact from coal mining and reclamation operations on the quality and quantity of surface or groundwater. The adverse impact must preclude any existing or reasonably foreseeable use of water outside the permit area. It further defines a ''quantifiable adverse impact'' as an effect that can be quantified and measured to a significant degree of confidence. Last, it states that ''existing or reasonably foreseeable uses of water'' are those beneficial uses recognized in title 75, chapter 5, part 3 of the MCA.

Next, in paragraph (b), Montana defines ''Material damage . . . with