

for under sections 1129 and 1140 of the Act might have a slight impact on small entities, it is the nature of the violation and not the size of the entity that will result in an action by the Office of Inspector General. Additionally, the Social Security Act requires the consideration of individual factors, including the financial condition of the person or entity committing the offense, in determining the CMP amount. Therefore, we do not anticipate that small entities will be significantly affected.

#### *Congressional Review Act*

Pursuant to the Congressional Review Act (5 U.S.C. 801*et seq.*) this rule is not a “major rule,” as defined by 5 U.S.C. 804(2).<sup>11</sup>

#### *E.O. 14192*

Based upon the criteria established in E.O. 14192 and OMB Memorandum M–25–20, this rule is not an “E.O. regulatory action” because it does not impose total costs greater than zero.<sup>12</sup>

#### *Paperwork Reduction Act*

These rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

#### **List of Subjects in 20 CFR Part 498**

Administrative practice and procedure, Fraud.

#### **Mark Steffensen,**

*General Counsel, Social Security Administration.*

#### **PART 498—CIVIL MONETARY PENALTIES, ASSESSMENTS AND RECOMMENDED EXCLUSIONS**

■ The interim final rule amending 20 CFR part 498, which was published at

<sup>11</sup> A “major rule” means any rule that the Administrator of the Office of the Information and Regulatory Affairs at OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of \$100 million or more; (b) a major increase in costs or prices for consumers, individual industries, Federal agencies, State agencies, local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprise to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 804(2)).

<sup>12</sup> According to M–25–20, an “E.O. 14192 regulatory action” is: (i) A significant regulatory action as defined in Section 3(f) of E.O. 12866 that has been finalized and that imposes total costs greater than zero; or (ii) A significant guidance document, broadly conceived, (e.g., significant interpretive guidance) reviewed by OIRA under the procedures of E.O. 12866 that has been finalized and that imposes total costs greater than zero.”

81 FR 41438 on June 27, 2016, is adopted as final without change.

[FR Doc. 2026–11585 Filed 6–9–26; 8:45 am]

**BILLING CODE 4191–02–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 874**

[Docket No. FDA–2026–N–6010]

#### **Medical Devices; Ear, Nose, and Throat Devices; Classification of the Combined Acoustic and Electrical External Stimulation Device for the Relief of Tinnitus**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the combined acoustic and electrical external stimulation device for the relief of tinnitus 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 combined acoustic and electrical external stimulation device for the relief of tinnitus. 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 10, 2026. The classification was applicable on March 6, 2023.

**FOR FURTHER INFORMATION CONTACT:** Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993–0002, 301–796–6481, *Shu-Chen.Peng@fda.hhs.gov*.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Upon request, FDA (the Agency or we) has classified the combined acoustic and electrical external stimulation device for the relief of tinnitus 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 August 18, 2021, FDA received Neuromod Devices Limited's request for De Novo classification of the Lenire 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 March 6, 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 874.3410.<sup>1</sup> We have named the generic type of device "combined acoustic and electrical external stimulation device for the relief of tinnitus," and it is identified as a device that provides acoustic stimulation in the ear and external, electrical stimulation of sensory nerves to relieve tinnitus.

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 COMBINED ACOUSTIC AND ELECTRICAL EXTERNAL STIMULATION DEVICE FOR THE RELIEF OF TINNITUS**

Identified risks to health	Mitigation measures
Adverse tissue reaction ..... Thermal and electrical safety: Injury from electrical current on skin or mucosa causing one or more of the following: <ul style="list-style-type: none"> <li>• Burn.</li> <li>• Irritation.</li> <li>• Electrical shock.</li> <li>• Pain.</li> <li>• Glandular hypersecretion.</li> <li>• Headache.</li> </ul>	Biocompatibility evaluation; and Labeling. Non-clinical performance testing; Clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; Electrical safety testing; Electromagnetic compatibility testing; Battery safety testing; and Labeling.
Increase in tinnitus or associated behavior issues during treatment ..... Hearing loss from overstimulation .....	Clinical performance testing; and Labeling. Non-clinical performance 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 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 combined acoustic and electrical external stimulation devices for the relief of tinnitus. 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

<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.

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 874

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 874 is amended as follows:

#### PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for part 874 continues to read as follows:

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

■ 2. Add § 874.3410 to subpart D to read as follows:

#### § 874.3410 Combined acoustic and electrical external stimulation device for the relief of tinnitus.

(a) *Identification.* A combined acoustic and electrical external stimulation device for the relief of tinnitus is a device that provides acoustic stimulation in the ear and external, electrical stimulation of sensory nerves to relieve tinnitus.

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

(1) Clinical performance testing must demonstrate performance as intended under anticipated conditions for use including the following:

(i) Evaluation of tinnitus symptoms using a validated method; and

(ii) Evaluation of all adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Verification of specified electrical stimulation parameters; and

(ii) Verification of specified acoustic stimulation parameters, including maximum output limits, distortion levels, and frequency response.

(3) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device.

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

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

(6) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use.

(7) Labeling must include the following:

(i) A statement that the device is intended to be prescribed by a healthcare professional with expertise in the evaluation and management of tinnitus;

(ii) Information regarding emotional, psychological, and physical considerations for patient selection; and

(iii) Device specifications, including the materials of patient-contacting components of the device, electrical output waveform, stimulation peak voltage and current, pulse duration, frequency, maximum current density, maximum phase charge, and power source.

**Grace R. Graham,**

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

[FR Doc. 2026–11589 Filed 6–9–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### 31 CFR Part 528

#### Publication of International Criminal Court-Related Sanctions Regulations Web General License 11

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Publication of a web general license.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a general license (GL) issued pursuant to the International Criminal Court-Related Sanctions Regulations: GL 11. This GL was previously made available on OFAC's website.

**DATES:** GL 11 was issued on December 18, 2025. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

**FOR FURTHER INFORMATION CONTACT:** OFAC: Assistant Director for Regulatory Affairs, 202–622–4855; or <https://ofac.treasury.gov/contact-ofac>.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Availability

This document and additional information concerning OFAC are

available on OFAC's website: <https://ofac.treasury.gov>.

#### Background

On December 18, 2025, OFAC issued GL 11 to authorize certain transactions otherwise prohibited by the International Criminal Court-Related Sanctions Regulations, 31 CFR part 528. This GL expired on January 17, 2026. This GL was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. The text of this GL is provided below.

#### OFFICE OF FOREIGN ASSETS CONTROL

#### International Criminal Court-Related Sanctions Regulations

#### 31 CFR Part 528

#### GENERAL LICENSE NO. 11

#### Authorizing the Wind Down of Transactions Involving Certain Persons Blocked on December 18, 2025

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the International Criminal Court-Related Sanctions Regulations (ICCSR), 31 CFR part 528, that are ordinarily incident and necessary to the wind down of any transaction involving one or more of the following blocked persons are authorized through 12:01 a.m. eastern standard time, January 17, 2026, provided that any payment to a blocked person is made into a blocked interest-bearing account located in the United States, in accordance with the ICCSR:

(1) Gocha Lordkipanidze;

(2) Erdenebalsuren Damdin; or

(3) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(b) This general license does not authorize any transactions otherwise prohibited by the ICCSR, including transactions involving any person blocked pursuant to the ICCSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Bradley T. Smith,

*Director, Office of Foreign Assets Control.*

Dated: December 18, 2025.

**Bradley T. Smith,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2026–11601 Filed 6–9–26; 8:45 am]

**BILLING CODE 4810–AL–P**