Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * *	
(vi) 8 to 10	Monensin, 5 to 30 plus decoquinate, 13.6 to 27.2.	Growing beef steers and heifers fed in confinement for slaughter: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* for improved feed efficiency, and for the reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes.*	Feed as the sole ration to provide 22.7 mg of decoquinate per 100 lb. of body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg tylosin (as tylosin phosphate). Feed for at least 28 days during periods of coccidiosis exposure or when experience indicates that coccidiosis is likely to be a hazard. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle feed is safe only for use in cattle. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. Do not use in feeds containing bentonite. Do not feed to cows producing milk for food. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; decoquinate as provided by No. 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.355(d).	016592 066104
*	*	*	* * *	

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07500 Filed 4–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2026–N–2959]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Transcutaneous Electrical Nerve Stimulator for the Relief of Congestion

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the transcutaneous electrical nerve stimulator for the relief of congestion 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 for the relief of congestion. 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 April 16, 2026. The classification was applicable on March 5, 2021.

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 transcutaneous electrical nerve stimulator for the relief of congestion as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. 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 as, 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 application 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 13, 2020, FDA received Tivic Health Systems Inc.'s request for De Novo classification of the ClearUP Sinus Relief 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, 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 5, 2021, 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 874.6000.[1] We have named the generic type of device ''transcutaneous electrical nerve stimulator for the relief of congestion,'' and it is identified as a device that electrically stimulates the skin overlying the paranasal sinuses to relieve congestion.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR FOR THE RELIEF OF CONGESTION

Identified risks to health	Mitigation measures
Injury from electrical current on face causing one or more of the following: • Skin burn • Skin redness • Skin irritation • Facial muscle twitching • Electrical shock • Pain • Headache • Discomfort or muscle twitching of the eye	Non-clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; Electrical safety testing; Electromagnetic compatibility testing; Battery safety testing; and Labeling.
Nerve and muscle injury	Non-clinical performance testing; Electrical safety testing; and Software verification, validation, and hazard analysis.
Ineffective treatment leading to worsening congestion	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. 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) (21 U.S.C. 360(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 the transcutaneous electrical nerve stimulator for the relief of congestion. 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 individually or cumulatively 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,

[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.

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 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 § 874.6000 to subpart F to read as follows:

§ 874.6000 Transcutaneous electrical nerve stimulator for the relief of congestion.

(a) *Identification.* A transcutaneous electrical nerve stimulator for the relief of congestion is a device that electrically stimulates the skin overlying the paranasal sinuses to relieve congestion.

(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, including electrical stimulation parameters that must be specified and verified.

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

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

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

(5) 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.

(6) Labeling must include the following:

(i) Instructions for use, including images that demonstrate how to use the device;

(ii) Device specifications, including the number of channels, output waveform, stimulation peak voltage and current, pulse duration, frequency, maximum current density, maximum phase charge, and power source; and

(iii) Explanations of the user-interface components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07365 Filed 4–15–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2026–N–2887]

Medical Devices; Orthopedic Devices; Classification of the Manual Surgical Instrument for Appropriate Patient Selection for Orthopedic Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the manual surgical instrument for appropriate patient selection for orthopedic implant 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 the classification of the manual surgical instrument for appropriate patient selection for orthopedic implant. 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 April 16, 2026. The classification was applicable on May 28, 2019.

FOR FURTHER INFORMATION CONTACT: David Hwang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4568, Silver Spring, MD 20993–0002, 301–796–3217, *David.Hwang@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the manual surgical instrument for appropriate patient selection for orthopedic implant as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based on the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days of announcing the classification.

Alternatively, under section 513(f)(6)(C) of the FD&C Act, a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to