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. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. At a future date, we may publish a separate notice in the **Federal Register** announcing our intent to exempt this device type.

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 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in the guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; and the collections of information in part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.1510 to subpart B to read as follows:

§ 876.1510 Anchored esophageal sheath.

(a) *Identification.* An anchored esophageal sheath is a device used to provide an endoluminal pathway to facilitate insertion of an endoscope or other compatible device into the upper gastrointestinal tract. A distal anchor assists in keeping the sheath in place to facilitate positioning of the endoscope or other compatible device.

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

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

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

(i) Testing must verify all dimensions;

(ii) Testing must demonstrate that insertion and removal of any device from the anchored esophageal sheath does not damage the shaft wall or exert force that would cause tissue injury;

(iii) Testing must demonstrate that the anchoring component can be reliably actuated;

(iv) Testing must demonstrate compatibility with any other device that the anchored esophageal sheath is intended to be used with; and

(v) Testing must demonstrate device integrity and functionality in simulated gastric conditions under clinically anticipated forces.

(3) Simulated use testing using an anatomically accurate gastrointestinal model must demonstrate that:

(i) The device can be inserted and removed safely;

(ii) The device remains anchored in place;

(iii) The device can be safely withdrawn after releasing the anchor; and

(iv) The device location and anchoring status can be observed by the intended user.

(4) Performance data must demonstrate continued device functionality over the identified shelf life.

(5) Labeling must include:

(i) Information as to whether the device can be used for foreign body removal or with instruments alongside the endoscope;

(ii) Steps needed to prevent injury to the esophagus or gastroesophageal junction (GEJ) during placement, anchoring, and use of the device;

(iii) Any visualization steps required to confirm the device's placement prior to and after actuating the anchoring component at the GEJ;

(iv) A precaution to avoid excessive force during insertion;

(v) Identification of any endoscopes or other devices that have been validated for use with the anchored esophageal sheath; and

(vi) An expiration date or shelf life.

Lowell M. Zeta,

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

[FR Doc. 2025–21217 Filed 11–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2025–N–4680]

Medical Devices; Neurological Devices; Classification of Field Generator Positioning Device

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 field generator positioning device into class I (general controls). We are taking this action because we have determined that classifying the device into class I (general controls) 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 November 26, 2025. The classification was applicable on July 10, 2020.

FOR FURTHER INFORMATION CONTACT: Payton Lin, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1212, Silver Spring, MD 20993–0002, 240–402–6580, *Payton.Lin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the field generator positioning device as class I (general 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), 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 the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days of announcing the classification.

II. Accessory Classification

On April 17, 2020, FDA received Stryker ENT's request for accessory classification of the TGS Universal Headrest with Mounting Arm. 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 I if general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device for its intended use (see section 513(a)(1)(A) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class I (general controls). FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 10, 2020, FDA issued an order to the requester classifying the device into class I. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.4565.[1] We have named the generic type of device ''field generator positioning device,'' and it is identified as a manual, mechanical device intended to position the field generator of an electromagnetic based stereotaxic navigation system in proximity to a patient. The device may operate independently or adapt existing medical equipment, such as a procedure chair or surgical bed, by using a mechanical interface.

FDA has identified the following risks to health associated specifically with this type of device: mechanical failure (which could damage the field generator or cause the device to physically impact the patient), interference from items within the projected field, or movement of the electromagnetic field projection.

Section 510(l)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(l)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 882.9.

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 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in the guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; and the collections of information in 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:

[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.

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, *360l,* 371.

■ 2. Add § 882.4565 to subpart E to read as follows:

§ 882.4565 Field generator positioning device.

(a) *Identification.* A field generator positioning device is a manual, mechanical device intended to position the field generator of an electromagnetic based stereotaxic navigation system in proximity to a patient. The device may operate independently or adapt existing medical equipment, such as a procedure chair or surgical bed, by using a mechanical interface.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

Lowell M. Zeta,

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

[FR Doc. 2025–21218 Filed 11–25–25; 8:45 am]

BILLING CODE 4164–01–P

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 559

RIN 3141–AA83

Facility License Notifications; Withdrawal

AGENCY: National Indian Gaming Commission

ACTION: Direct final rule; withdrawal.

SUMMARY: Due to the receipt of adverse comments, the National Indian Gaming Commission (NIGC) is withdrawing the direct final rule ''Facility License Notifications,'' published September 29, 2025.

DATES: Effective November 24, 2025, the direct final rule published at 90 FR 46470, September 29, 2025, is withdrawn.

FOR FURTHER CONTACT INFORMATION CONTACT: Jo-Ann M. Shyloski, Office of General Counsel at the National Indian Gaming Commission, at (202) 632–7003 or *info@nigc.gov.*

SUPPLEMENTARY INFORMATION: On September 29, 2025, the NIGC published a direct final rule (90 FR 46470). We stated in that direct final rule that if we received adverse comments by October 29, 2025, the direct final rule would not take effect, and we would publish a timely withdrawal in the **Federal Register**. The NIGC subsequently received adverse comments on that direct final rule and is therefore withdrawing this direct final rule. The NIGC may issue a notice of proposed rulemaking in a future edition of the **Federal Register** to initiate action to repromulgate the rule that is withdrawn today. In any such action, the NIGC would address the adverse comments it received on the direct final rule.

National Indian Gaming Commission.

Sharon M. Avery,

Acting Chairwoman.

Jean Hovland,

Vice Chair.

[FR Doc. 2025–21347 Filed 11–25–25; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

[Docket No. VA–2024–OTHER–0024]

RIN 2900–AS18

Extending Deadline for Debtor To Request a Waiver

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is finalizing, with technical changes, a proposed rule to amend the time period that a debtor has to request a waiver from 180 days to one year, as mandated by the Cleland Dole Act. Generally, VA is authorized to not recover debts related to benefits payments or overpayments where recovery would be against good conscience and an application for relief is made within the required time period. Allowing an additional six months to request a waiver reduces pressure on veterans by easing the compliance burden.

DATES: This rule is effective on January 26, 2026.

FOR FURTHER INFORMATION CONTACT: Jeremiah Mcintosh, Systems and Procedures Analyst, Office of Finance, Office of Management, (207) 402–9017.

SUPPLEMENTARY INFORMATION: On November 8, 2024, VA published a proposed rule in the **Federal Register**, 89 FR 88686, to amend the time period that a debtor has to request a waiver from 180 days to one year consistent with section 254 of the Cleland Dole Act, Public Law 117–328, Division U, which went into effect on December 29, 2024. VA provided a 60-day comment period, which ended on January 7, 2025. VA received one supportive comment, which also contained a request that was outside the scope of the rulemaking. VA is not making any changes to the final regulation based on this comment. For the reasons stated above, VA will adopt the proposed rule as final, with technical changes.

Technical Changes Not Related to Comments

Currently, 38 CFR 1.963(b)(1) establishes a two-year timeframe for individuals to submit a request for waiver from indebtedness for VA notices of indebtedness issued by VA on or before March 31, 1983, without any exception to extend this timeframe. This two-year timeframe was consistent with 38 U.S.C. 5302(a), prior to such statute being amended to substitute ''180 days'' for the former ''two years,'' and to newly include an exception to extend the 180-day timeframe if an individual could show their receipt of VA's notice was delayed. See Public Law 97–306, sec. 407(b), enacted Oct. 14, 1982, effective March 31, 1983.

Subject to this statutory amendment, VA promulgated § 1.963(b)(2) on June 15, 1983, establishing a new timeframe of 180 days from the date of VA notice for those notices issued by VA after March 31, 1983, and including a new exception to extend that timeframe. 48 FR 27400. At the time that VA first promulgated § 1.963(b)(2), this new 180-day timeframe overlapped the former two-year timeframe in § 1.963(b)(1), and so VA retained paragraph (b)(1) to ensure that the former, longer timeframe had adequate time to run. However, paragraph (b)(1) is now obsolete as the former two-year timeframe for notices of indebtedness issued by VA on or prior to March 31, 1983, has long since passed, and there is no statutory exception to extend that two-year timeframe for such notices. VA therefore removes paragraph (b)(1) of § 1.963 in this final rule. In so doing, VA will now only regulate applicable timeframes for individuals to submit requests for waivers of indebtedness in a single paragraph (b) under § 1.963.

VA proposed to revise § 1.963(b)(1) to replace the former 180-day timeframe with one year for *all* notices issued by VA after April 1, 1983, so that application of waiver can be ''made within one year following the date of a notice of indebtedness issued on or after April 1, 1983, by the Department of Veterans Affairs to the debtor.'' 89 FR 88687. This proposed revision was based on amendments to 38 U.S.C.