have raised concerns about whether a sentence in the preamble of the final rule could be read as changing existing interpretations related to accepting or receiving deposits. The sentence is italicized below: [1]

The FDIC recognizes that the statute only limits the amount of reciprocal deposits an institution may ''receive'' in order to be considered an agent institution. *Thus, an institution that is less than well capitalized or not well rated will still qualify as an agent institution if it holds a level of reciprocal deposits above the special cap, as long as (1) such deposits were received before the institution became less than well capitalized or not well rated, (2) such deposits are time deposits,*[28] *and (3) the institution satisfies all other qualifications necessary to be an agent institution.* For example, an institution that is well capitalized but no longer well rated could continue to be an agent institution if it holds reciprocal time deposits that it received prior to its rating downgrade until those time deposits mature or roll off, but would no longer be an agent institution if it renewed or rolled over such deposits and doing so caused the total amount of reciprocal deposits to exceed the special cap. In this case, once the institution receives reciprocal deposits in excess of its special cap, it is no longer an agent institution. If an institution is not an agent institution, all of its reciprocal deposits should be reported as brokered deposits.

* * * * *

[28] Transactional reciprocal deposits are viewed as being received daily.

The FDIC does not intend this preamble language to change existing interpretations related to accepting or receiving deposits. Therefore, in an effort to avoid confusion, the FDIC is deleting the sentence in question along with its corresponding footnote and, amending the sentence that immediately follows. The revised paragraph reads as follows:

The FDIC recognizes that the statute only limits the amount of reciprocal deposits an institution may ''receive'' in order to be considered an agent institution. To take a simple example, an institution that is well capitalized but no longer well rated could continue to be an agent institution if it holds reciprocal certificate of deposits that it received prior to its rating downgrade until those certificate of deposits mature or roll off, but would no longer be an agent institution if it renewed or rolled over such deposits and doing so caused the total amount of reciprocal deposits to exceed the special cap. In this case, once the institution receives reciprocal deposits in excess of its special cap, it is no longer an agent institution. If an institution is not an agent institution, all of its reciprocal deposits should be reported as brokered deposits.

As discussed above, these changes to the preamble text are technical, and do not change the rule text. Accordingly, the FDIC finds that notice and comment procedures are unnecessary. Further, because the changes are technical, delaying the effective date would serve no purpose. Therefore, these changes will be effective upon publication.

For convenient reference, the FDIC is posting the revised preamble and final rule in their entirety on its website.

* * * * *

Dated at Washington, DC, on March 8, 2019.

By Order of the Board of Directors.

Federal Deposit Insurance Corporation.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2019–07048 Filed 4–12–19; 8:45 am]

BILLING CODE 6714–01–P

[1] 84 FR 1346, 1349 (February 4, 2019).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2019–N–0647]

Medical Devices; Anesthesiology Devices; Classification of the Ventilatory Electrical Impedance Tomograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the ventilatory electrical impedance tomograph 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 ventilatory electrical impedance tomograph's classification. We are taking this action because we have determined that classifying the device into class II (special 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 April 15, 2019. The classification was applicable on December 20, 2018.

FOR FURTHER INFORMATION CONTACT: Deepika Arora Lakhani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2560, Silver Spring, MD 20993–0002, 301–796–4042, *Deepika.Lakhani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the ventilatory electrical impedance tomograph 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 (see 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 by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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. 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 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 29, 2017, TIMPEL Inc. submitted a request for De Novo classification of the ENLIGHT 1810. 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 21 U.S.C. 360c(a)(1)(B)). 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 December 20, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 868.1505. We have named the generic type of device ventilatory electrical impedance tomograph, and it is identified as a prescription non-invasive, non-radiological ventilatory device that provides an assessment of local impedance variation within a cross-section of a patient's thorax.

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—VENTILATORY ELECTRICAL IMPEDANCE TOMOGRAPH RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measure
Adverse tissue reaction	Biocompatibility evaluation.
Electromagnetic interference with other devices	Electromagnetic compatibility testing.
Infection	Reprocessing validation and Labeling.
Inaccurate images due to either device hardware or software failure/malfunction.	Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling.
Electrical shock injury or thermal injury	Electrical, thermal, and mechanical safety testing; Software verification, validation, and hazard analysis; 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. 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 order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, ventilatory electrical impedance tomographs 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 (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

We have 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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; 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 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; 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 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

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

■ 2. Add § 868.1505 to subpart B to read as follows:

§ 868.1505 Ventilatory electrical impedance tomograph.

(a) *Identification.* A ventilatory electrical impedance tomograph is a prescription non-invasive, non-radiological ventilatory device that provides an assessment of local impedance variation within a cross-section of a patient's thorax.

(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, including the following:

(i) Characterization of device parameters, including signal-to-noise ratio, voltage accuracy, drift, reciprocity accuracy, amplitude response, position error, and ringing;

(ii) Real time evaluation of local impedance variation;

(iii) Plethysmogram accuracy testing; and

(iv) Use life testing of reusable components.

(3) Performance data must validate reprocessing instructions for any reusable components of the device.

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

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

(6) Labeling must include the following:

(i) Guidance for interpretation of the images generated;

(ii) A warning that the device should be removed before use of a defibrillator, or defibrillator interaction information based on defibrillator performance testing with the device;

(iii) A use life for any reusable components; and

(iv) Instructions for reprocessing any reusable components.

Dated: April 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07463 Filed 4–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[192A2100DD/AAKC001030/A0A501010.999900253G]

25 CFR Parts 140, 141, 211, 213, 225, 226, 227, 243, and 249

RIN 1076–AF40

Civil Penalties Inflation Adjustments; Annual Adjustments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule provides for annual adjustments to the level of civil monetary penalties contained in Bureau of Indian Affairs (Bureau) regulations to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on April 15, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Director, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs; telephone (202) 273–4680, *elizabeth.appel@bia.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (''the Act''). The Act requires Federal agencies to adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

The Office of Management and Budget (OMB) issued guidance for Federal agencies on calculating the catch-up adjustment. *See* February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–16–06). Under the guidance, the Department identified applicable civil monetary penalties and calculated the catch-up adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated catch-up adjustment is based on the percent change between the Consumer Price Index for all Urban Consumers (CPI0–U) for the month of October in the year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI–U.

The Bureau issued an interim final rule providing for calculated catch-up adjustments on June 30, 2016 (81 FR 42478) with an effective date of August 1, 2016, and requesting comments post-promulgation. The Bureau issued a final rule affirming the catch-up adjustments set forth in the interim final rule on December 2, 2016 (81 FR 86953). The Bureau then issued a final rule making the next scheduled annual inflation adjustment for 2017 on January 23, 2017 (82 FR 7649) and for 2018 on February 6, 2018 (83 FR 5192).

II. Calculation of 2019 Annual Adjustments

OMB recently issued guidance to assist Federal agencies in implementing the annual adjustments required by the Act which agencies must complete by January 15, 2019. *See* December 14, 2018, Memorandum for the Heads of Executive Departments and Agencies, from Mick Mulvaney, Director, Office of Management and Budget, re: *Implementation of the Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of*