Official Methods of Analysis, 21st edition, 2019.

(ii) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study, Katherine S. Carlos and Lowri S. De Jager; *Journal of AOAC International,* Vol. 100, No. 6, 2017, pp. 1785–1794.

(2) [Reserved]

Appendix A to Part 101 [Removed and Reserved]

■ 3. Remove and reserve appendix A to part 101.

PART 130—FOOD STANDARDS: GENERAL

■ 4. The authority citation for part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

■ 5. Amend § 130.9 by revising paragraph (a) and adding paragraph (c) to read as follows:

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable concentration is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million (ppm or mg/kg) or more of the sulfite in the finished food. The concentration of sulfite in the finished food will be determined using either:

(1) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry; or

(2) AOAC Official Method 990.28.

* * * * *

(c) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method, Section 47.3.43, Official Methods of Analysis, 21st edition, 2019.

(2) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study, Katherine S. Carlos and Lowri S. De Jager; *Journal of AOAC International,* Vol. 100, No. 6, 2017, pp. 1785–1794.

Dated: January 11, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00816 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2021–N–0914]

Medical Devices; Cardiovascular Devices; Classification of the Electrocardiograph Software for Over-the-Counter Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the electrocardiograph software for over-the-counter use 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 electrocardiograph software for over-the-counter use'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.

DATES: This order is effective January 18, 2022. The classification was applicable on September 11, 2018.

FOR FURTHER INFORMATION CONTACT: Luke Ralston, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2311, Silver Spring, MD 20993–0002, 301–796–6362, *Luke.Ralston@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the electrocardiograph software for over-the-counter use 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, 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 (see 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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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. 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 14, 2018, FDA received Apple Inc.'s request for De Novo classification of the ECG App. 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 September 11, 2018, 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 870.2345.[1] We have named the generic type of device electrocardiograph software for over-the-counter use, and it is identified as a device that creates, analyzes, and displays electrocardiograph data and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

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—ELECTROCARDIOGRAPH SOFTWARE FOR OVER-THE-COUNTER USE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Poor quality electrocardiograph (ECG) signal resulting in failure to detect arrhythmia.	Clinical performance testing, Human factors testing, and Labeling.
Misinterpretation and/or over-reliance on device output, leading to: • Failure to seek treatment despite acute symptoms • Discontinuing or modifying treatment for chronic heart condition	Human factors testing, and Labeling.
False negative resulting in failure to identify arrhythmia and delay of further evaluation or treatment.	Clinical performance testing, Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling.
False positive resulting in additional unnecessary medical procedures ..	Clinical performance 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.

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 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 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 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 870

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 870 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 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.2345 to subpart C to read as follows:

§ 870.2345 Electrocardiograph software for over-the-counter use.

(a) *Identification.* An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

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

(1) Clinical performance testing under anticipated conditions of use must demonstrate the following:

(i) The ability to obtain an electrocardiograph of sufficient quality for display and analysis; and

(ii) The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

(iv) A description of what the device measures and outputs to the user; and

(v) Guidance on interpretation of any results.

Dated: January 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00827 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 575

Annual Adjustment of Civil Monetary Penalty To Reflect Inflation

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: In compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the Act) and Office of Management and Budget (OMB) guidance, the National Indian Gaming Commission (NIGC or Commission) is amending its civil monetary penalty rule to reflect an annual adjustment for inflation in order to improve the penalty's effectiveness and maintain its deterrent effect. The Act provides that the new penalty level must apply to penalties assessed after the effective date of the increase, including when the penalties whose associated violation predate the increase.

DATES: This rule is effective January 18, 2022. This final rule is applicable beginning on January 15, 2022.

FOR FURTHER INFORMATION CONTACT: Armando J. Acosta, Senior Attorney, Office of General Counsel, National Indian Gaming Commission, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

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). Beginning in 2017, the Act requires agencies to make annual inflationary adjustments to their civil monetary penalties by January 15th of each year, in accordance with annual OMB guidance.

II. Calculation of Annual Adjustment

In December of every year, OMB issues guidance to agencies to calculate the annual adjustment. According to OMB, the cost-of-living adjustment multiplier for fiscal year 2022 is 1.06222, based on the Consumer Price Index for the month of October 2021, not seasonally adjusted.

Pursuant to this guidance, the Commission has calculated the annual adjustment level of the civil monetary penalty contained in 25 CFR 575.4 (''The Chairman may assess a civil fine, not to exceed $54,157 per violation, against a tribe, management contractor, or individual operating Indian gaming for each notice of violation . . .''). The 2022 adjusted level of the civil monetary penalty is $57,527 ($54,157 × 1.06222).

III. Regulatory Matters

Regulatory Planning and Review

This final rule is not a significant rule under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy or will not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not involve entitlements, grants, user fees, or loan programs or the rights or obligations of recipients.

(4) This regulatory change does not raise novel legal or policy issues.

Regulatory Flexibility Act

The Commission certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule makes annual adjustments for inflation.

Small Business Regulatory Enforcement Fairness Act

This final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year. The rule will not result in a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This final rule does not impose an unfunded mandate of more than $100 million per year on state, local, or tribal