Department of Commerce revised its regulations on antidumping and countervailing duty proceedings to conform to the Uruguay Round Agreements Act (62 FR 27296) (May 19, 1997) which resulted in a new part 351 and the deletion of parts 353 and 355. Accordingly, this document makes conforming changes to §§ 159.58(a) and 159.58(b) to reflect this revision.

Part 181

Subpart D of Part 181 of title 19 deals with post-importation duty refund claims under the North American Free Trade Agreement (NAFTA). Section 181.33(d)(1) lists instances wherein a port director may deny a post-importation duty refund claim for preferential tariff treatment for imported goods under the NAFTA, and it references § 181.32(b)(3) in the context of the validity of a Certificate of Origin. This is not the correct reference. The proper reference should be to § 181.32(b)(2), which references the requirement to file a Certificate of Origin with respect to the imported goods. Accordingly, this document makes changes to § 181.33(d)(1) to reference § 181.32(b)(2) instead of § 181.32(b)(3).

Inapplicability of Notice and Delayed Effective Date

As the technical corrections set forth in this document merely conform to existing law and regulation, CBP finds that good cause exists for dispensing with notice and public procedure as unnecessary under 5 U.S.C. 553(b)(B). For this same reason, pursuant to 5 U.S.C. 553(d)(3), CBP finds that good cause exists for dispensing with the requirement for a delayed effective date.

Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12866

These amendments do not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866, as supplemented by Executive Order 13563.

Signing Authority

This document is limited to technical corrections of the CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b)(1).

List of Subjects

19 CFR Part 159

Alcohol and alcohol beverages, Antidumping (Liquidation of duties), Cigars and cigarettes, Computer technology, Countervailing duties (Liquidation of duties), Customs duties and inspection, Discriminating duties, Entry procedures, Foreign currencies, Import, Liquidation of entries for merchandise, Suspension of liquidation pending disposition of American manufacturer's cause of action, Value content.

19 CFR Part 181

Administrative practice and procedure, Canada, Customs duties and inspection, Exports, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements (North American Free-Trade Agreements).

Amendments to the Regulations

For the reasons set forth above, parts 159 and 181 of the CBP regulations (19 CFR parts 159 and 181) are amended as set forth below.

PART 159—LIQUIDATION OF DUTIES

■ 1. The general authority citation for part 159 continues to read as follows:

Authority: 19 U.S.C. 66, 1500, 1504, 1624.

* * * * *

§ 159.58 [Amended]

■ 2. Section 159.58 is amended:

■ a. In paragraph (a) by removing the term ''part 353'' and adding in its place the term ''part 351''; and

■ b. In paragraph (b) by removing the term ''part 355'' and adding in its place the term ''part 351''.

PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

■ 3. The authority citation for part 181 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624, 3314.

Subpart D of part 181 also issued under 19 U.S.C. 1520(d).

§ 181.33 [Amended]

■ 4. Section 181.33(d)(1) is amended by removing the citation ''§ 181.32(b)(3)'' and adding in its place the citation ''§ 181.32(b)(2)''.

Dated: July 24, 2017.

Kevin K. McAleenan,

Acting Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2017–15888 Filed 7–27–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2017–N–1620]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Cardiovascular Status Indicator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the adjunctive cardiovascular status indicator into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the adjunctive cardiovascular status indicator's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on December 21, 2016.

FOR FURTHER INFORMATION CONTACT: Nathalie Yarkony, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1254, Silver Spring, MD 20993–0002, 301–796–1235, *nathalie.yarkony@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On May 24, 2016, Flashback Technologies submitted a request for classification of the CipherOx CRI Tablet under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 21, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 870.2200.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an adjunctive cardiovascular status indicator will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name adjunctive cardiovascular status indicator, and it is identified as a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

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—ADJUNCTIVE CARDIOVASCULAR STATUS INDICATOR RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error.	Software verification, validation, and hazard analysis. Non-clinical performance testing. Clinical performance testing. Labeling.
Delayed or incorrect treatment due to user misinterpretation	Usability assessment. Labeling.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Adjunctive cardiovascular status indicators are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 *Prescription devices*).

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 FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA believes premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, is planning to exempt the device from the premarket notification requirements under section 510(m) of the FD&C Act. Once finalized, persons who intend to market this device type need not submit a 510(k) premarket notification containing information on the adjunctive cardiovascular status indicator prior to marketing the device.

II. 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.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of

information found in other FDA regulations. 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 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 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:

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 § 870.2200 to subpart C to read as follows:

§ 870.2200 Adjunctive cardiovascular status indicator.

(a) *Identification.* The adjunctive cardiovascular status indicator is a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

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

(1) Software description, verification, and validation based on comprehensive hazard analysis must be provided, including:

(i) Full characterization of technical parameters of the software, including any proprietary algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures; and

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports.

(2) Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.

(4) Clinical data must be provided in support of the intended use and include the following:

(i) Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner;

(ii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;

(iii) Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range; and

(iv) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.

(5) Labeling must include the following:

(i) The type of sensor data used, including specification of compatible sensors for data acquisition;

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

(iii) Warnings identifying sensor reading acquisition factors that may impact measurement results;

(iv) Guidance for interpretation of the measurements, including warning(s) specifying adjunctive use of the measurements;

(v) Key assumptions made in the calculation and determination of measurements;

(vi) The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance; and

(vii) A detailed description of the patients studied in the clinical validation (*e.g.,* age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15901 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–1609]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the oral removable palatal space occupying device for weight management and/or weight loss into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the oral removable palatal space occupying device for weight management and/or weight loss classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on September 26, 2016.

FOR FURTHER INFORMATION CONTACT: Mark Antonino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G208, Silver Spring, MD, 20993–0002, 240–402–9980, *mark.antonino@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially