Cleveland, OH, Cuyahoga County, ILS OR LOC RWY 24, Amdt 16A
Columbus, OH, Rickenbacker Intl, NDB RWY 5R, Amdt 2A, CANCELED
Columbus, OH, Rickenbacker Intl, NDB RWY 23L, Amdt 2A, CANCELED
Youngstown-Warren, OH, Youngstown-Warren Rgnl, RADAR 1, Amdt 14
Tulsa, OK, Tulsa Intl, ILS OR LOC RWY 18L, Amdt 16A
Tulsa, OK, Tulsa Intl, RNAV (GPS) RWY 8, Amdt 2B
Clarion, PA, Clarion County, VOR–A, Amdt 3A, CANCELED
Corry, PA, Corry-Lawrence, NDB RWY 14, Amdt 5, CANCELED
Franklin, PA, Venango Rgnl, VOR RWY 3, Amdt 5B, CANCELED
Harrisburg, PA, Harrisburg Intl, ILS OR LOC RWY 31, Amdt 1E
Hazleton, PA, Hazleton Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3
West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 9, Amdt 1A
West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 27, Amdt 1A
West Chester, PA, Brandywine Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1A
West Chester, PA, Brandywine Rgnl, VOR–A, Amdt 4A
York, PA, York, RNAV (GPS) RWY 17, Amdt 2C
York, PA, York, RNAV (GPS) RWY 35, Amdt 1C
Greenville, SC, Greenville Downtown, ILS Y OR LOC Y RWY 1, Orig-B
Greenville, SC, Greenville Downtown, ILS Z OR LOC Z RWY 1, Amdt 30B
Orangeburg, SC, Orangeburg Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Pierre, SD, Pierre Rgnl, ILS OR LOC RWY 31, Amdt 12D
Albany, TX, Albany Muni, RNAV (GPS) RWY 17, Amdt 1C
Albany, TX, Albany Muni, RNAV (GPS) RWY 35, Amdt 1C
Baytown, TX, RWJ Airpark, Takeoff Minimums and Obstacle DP, Amdt 1A
Borger, TX, Hutchinson County, VOR RWY 17, Amdt 9, CANCELED
Borger, TX, Hutchinson County, VOR/DME RWY 35, Amdt 4A, CANCELED
Fredericksburg, TX, Gillespie County, Takeoff Minimums and Obstacle DP, Amdt 2
Galveston, TX, Scholes Intl at Galveston, ILS OR LOC RWY 14, Amdt 12C
Galveston, TX, Scholes Intl at Galveston, VOR RWY 14, Amdt 4C
Haskell, TX, Haskell Muni, RNAV (GPS)-A, Orig-A
Houston, TX, Conroe-North Houston Rgnl, ILS OR LOC RWY 14, Amdt 3C
Houston, TX, Conroe-North Houston Rgnl, NDB RWY 14, Amdt 3C
Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 8L, ILS RWY 8L SA CAT I, ILS RWY 8L CAT II, ILS RWY 8L CAT III, Amdt 4D
Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 9, ILS RWY 9 SA CAT I, ILS RWY 9 SA CAT II, Amdt 10B
Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 26L, ILS RWY 26L SA CAT I, ILS RWY 26L CAT II, ILS RWY 26L CAT III, Amdt 21D
Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 26R, ILS RWY 26R SA CAT I, ILS RWY 26R CAT II, ILS RWY 26R CAT III, Amdt 4B
Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 27, ILS RWY 27 SA CAT I, ILS RWY 27 CAT II, ILS RWY 27 CAT III, Amdt 11A
Houston, TX, Pearland Rgnl, VOR–B, Amdt 1A, CANCELED
Houston, TX, William P Hobby, ILS OR LOC RWY 4, ILS RWY 4 SA CAT I, ILS RWY 4 CAT II, ILS RWY 4 CAT III, Amdt 43A
Houston, TX, William P Hobby, ILS OR LOC RWY 13R, Amdt 12D
Houston, TX, William P Hobby, ILS OR LOC RWY 31L, Amdt 6D
La Porte, TX, La Porte Muni, VOR–A, Orig-B, CANCELED
Olney, TX, Olney Muni, RNAV (GPS) RWY 17, Amdt 1
Olney, TX, Olney Muni, RNAV (GPS) RWY 35, Amdt 1
Brookneal, VA, Brookneal/Campbell County, RNAV (GPS) RWY 24, Amdt 1B
Brookneal, VA, Brookneal/Campbell County, VOR–A, Amdt 2A
Norfolk, VA, Chesapeake Rgnl, VOR/DME RWY 23, Amdt 1A, CANCELED
Petersburg, VA, Dinwiddie County, Takeoff Minimums and Obstacle DP, Amdt 1
Burlington, WI, Burlington Muni, RNAV (GPS) RWY 11, Orig-C
Burlington, WI, Burlington Muni, RNAV (GPS) RWY 29, Amdt 1C
Park Falls, WI, Park Falls Muni, NDB RWY 36, Amdt 1A, CANCELED
Platteville, WI, Platteville Muni, RNAV (GPS) RWY 7, Orig-C
Platteville, WI, Platteville Muni, RNAV (GPS) RWY 25, Orig-A
Bluefield, WV, Mercer County, ILS OR LOC RWY 23, Amdt 15D

Rescinded: On February 7, 2019 (84 FR 2441), the FAA published an Amendment in Docket No. 31229, Amdt No. 3831, to Part 97 of the Federal Aviation Regulations under section 97.33. The following entry for College Station, TX, effective February 28, 2019, is hereby rescinded in its entirety:

College Station, TX, Easterwood Field, RNAV (GPS) RWY 29, Amdt 1B

[FR Doc. 2019–02679 Filed 2–19–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2019–N–0142]

Medical Devices; Dental Devices; Classification of the Auto Titration Device for Oral Appliances

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the auto titration device for oral appliances 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 auto titration device for oral appliances' 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 February 20, 2019. The classification was applicable on August 23, 2018.

FOR FURTHER INFORMATION CONTACT: Anita Belani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G314, Silver Spring, MD 20993–0002, 301–796–3944, *Anita.Belani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the auto titration device for oral appliances 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 (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 (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 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 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

For this device, FDA issued an order on November 23, 2016, finding the MATRx plus not substantially equivalent to a predicate not subject to premarket approval application. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On December 21, 2017, Zephyr Sleep Technologies submitted a request for De Novo classification of the MATRx plus. 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 August 23, 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 872.5571. We have named the generic type of device auto titration device for oral appliances, and it is identified as a prescription home use device that determines a target position to be used for a final oral appliance for the reduction of snoring and mild to moderate obstructive sleep apnea.

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—AUTO TITRATION DEVICE FOR ORAL APPLIANCES RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Reprocessing validation and Labeling.
Intraoral/temporomandibular joint injury, irritation, or pain due to: • Use error • Algorithm-directed positioning • Interference with other devices • Device electrical failure	Clinical performance testing; Human factors assessment; Non-clinical performance testing; Software verification, validation, and hazard analysis; Electrical safety testing; Electromagnetic compatibility testing; and Wireless coexistence testing.
Incorrect titration level due to use error	Human factors assessment and Labeling.
Disruption of sleep	Labeling.
Temporary change in bite or dentition	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, auto titration devices for oral appliances 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

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. 3501–3520). 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 872

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 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for part 872 continues to read as follows:

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

■ 2. Add § 872.5571 to subpart F to read as follows:

§ 872.5571 Auto titration device for oral appliances.

(a) *Identification.* An auto-titration device for oral appliances is a prescription home use device that determines a target position to be used for a final oral appliance for the reduction of snoring and mild to moderate obstructive sleep apnea.

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

(1) Clinical performance testing must evaluate the following:

(i) Performance characteristics of the algorithm; and

(ii) All adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:

(i) Validation of the closed loop algorithm;

(ii) Mechanical integrity over the expected use life;

(iii) Characterization of maximum force, distance, and speed of device movement; and

(iv) Movement accuracy of intraoral components.

(3) Performance testing must demonstrate the wireless compatibility, electrical safety, and electromagnetic compatibility of the device in its intended use environment.

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

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

(6) Performance data must validate the reprocessing instructions for any reusable components.

(7) Patient labeling must include:

(i) Information on device use, including placement of sensors and mouthpieces;

(ii) A description of all alarms; and

(iii) Instructions for reprocessing any reusable components.

(8) A human factors assessment must evaluate simulated use of the device in a home use setting.

Dated: February 14, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02824 Filed 2–19–19; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0596; FRL–9989–56–Region 10]

Air Plan Approval; OR: Lane County Outdoor Burning and Enforcement Procedure Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving and incorporating by reference into the Oregon State Implementation Plan (SIP) the Lane Regional Air Protection Agency's (LRAPA) revised outdoor burning rule submitted by the Oregon Department of Environmental Quality (ODEQ) on July 19, 2018. The revised rule, as it applies in Lane County, Oregon, clarifies terminology and provides additional controls of outdoor burning activities, reducing particulate emissions and strengthening the Oregon SIP. In addition, the EPA is approving but not incorporating by reference the enforcement procedures and civil penalties rule for LRAPA submitted by the ODEQ on September 25, 2018. The revised rule brings the enforcement procedures and civil penalties rule, as it applies in Lane County, into alignment with recent changes in Oregon State regulations.

DATES: This final rule is effective March 22, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0596. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Christi Duboiski at (360) 753–9081, or *duboiski.christi@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

Table of Contents

I. Background
II. Response to Comment
III. Final Action
IV. Incorporation by Reference
V. Oregon Notice Provision
VI. Statutory and Executive Order Reviews

I. Background

On July 19, 2018 and September 25, 2018, the ODEQ and LRAPA submitted revisions to the Oregon SIP as they apply in Lane County. On November 18, 2018, the EPA proposed to approve the LRAPA Title 47 outdoor burning rule which provided clarification and additional controls of outdoor burning activities in Lane County (83 FR 60836).