Cleveland, OH, Cuyahoga County, ILS OR LOC RWY 24, Amtd 16A
Columbia, OH, Rickenbacker Intl, NDB RWY 5R, Amtd 2A, CANCELED
Columbia, OH, Rickenbacker Intl, NDB RWY 23L, Amtd 2A, CANCELED
Youngstown-Warren, OH, Youngstown-Warren Rgnl, RADAR 1, Amtd 14
Tulsa, OK, Tulsa Intl, ILS OR LOC RWY 18L, Amtd 16A
Tulsa, OK, Tulsa Intl, RNAV (GPS) RWY 8, Amtd 2B
Clarion, PA, Clarion County, VOR–A, Amtd 3A, CANCELED
Corry, PA, Corry-Lawrence, NDB RWY 14, Amtd 5, CANCELED
Franklin, PA, Venango Rgnl, VOR RWY 3, Amtd 6C, CANCELED
Harrissburg, PA, Harrisburg Intl, ILS OR LOC RWY 31, Amtd 1E
Hazleton, PA, Hazleton Rgnl, Takeoff Minimums and Obstacle DP, Amtd 3
West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 19, Amtd 1A
West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 27, Amtd 1A
West Chester, PA, Brandywine Rgnl, Takeoff Minimums and Obstacle DP, Amtd 1A
West Chester, PA, Brandywine Rgnl, VOR–A, Amtd 4A
York, PA, York, RNAV (GPS) RWY 17, Amtd 2C
York, PA, York, RNAV (GPS) RWY 35, Amtd 1C
Greenville, SC, Greenville Downtown, ILS OR LOC Y RWY 1, Orig-B
Greenville, SC, Greenville Downtown, ILS OR LOC Z RWY 1, Amtd 30B
Orangeburg, SC, Orangeburg Muni, Takeoff Minimums and Obstacle DP, Amtd 4
Pierie, SD, Pierre Rgnl, ILS OR LOC RWY 31, Amtd 12D
Albany, TX, Albany Muni, RNAV (GPS) RWY 17, Amtd 1C
Albany, TX, Albany Muni, RNAV (GPS) RWY 35, Amtd 1C
Baytown, TX, RWJ Airpark, Takeoff Minimums and Obstacle DP, Amtd 1A
Borger, TX, Hutchinson County, VOR RWY 17, Amtd 9, CANCELED
Borger, TX, Hutchinson County, VOR/DME RWY 35, Amtd 4A, CANCELED
Fredericksburg, TX, Gillespie County, Takeoff Minimums and Obstacle DP, Amtd 2
Galveston, TX, Scholes Intl at Galveston, ILS OR LOC RWY 14, Amtd 12C
Galveston, TX, Scholes Intl at Galveston, VOR RWY 14, Amtd 4C
Haskell, TX, Haskell Muni, RNAV (GPS)-A, Orig-A
Houston, TX, Conroe-North Houston Rgnl, ILS OR LOC RWY 14, Amtd 3C
Houston, TX, Conroe-North Houston Rgnl, NDB RWY 14, Amtd 3C
Houston, TX, George Bush Intercontinental/ Houston, ILS OR LOC RWY 8, ILS RWY 8L SA CAT I, ILS RWY 8L CAT II, ILS RWY 8L CAT III, Amtd 4D
Houston, TX, George Bush Intercontinental/ Houston, ILS OR LOC RWY 9, ILS RWY 9 SA CAT I, ILS RWY 9 SA CAT II, ILS RWY 9 CAT II, Amtd 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, Amtd 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, Amtd 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, Amtd 11A
Houston, TX, Pearland Rgnl, VOR–B, Amtd 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, Amtd 43A
Houston, TX, William P Hobby, ILS OR LOC RWY 13R, Amtd 12D
Houston, TX, William P Hobby, ILS OR LOC RWY 31L, Amtd 6D
La Porte, TX, La Porte Muni, VOR–A, Orig-B, CANCELED
Olney, TX, Olney Muni, RNAV (GPS) RWY 17, Amtd 1
Olney, TX, Olney Muni, RNAV (GPS) RWY 35, Amtd 1
Brookeville, VA, Brookeville/Campbell County, RNAV (GPS) RWY 24, Amtd 1B
Brookeville, VA, Brookeville/Campbell County, VOR–A, Amtd 2A
Norfolk, VA, Chesapeake Rgnl, VOR/DEME RWY 23, Amtd 1A, CANCELED
Petersburg, VA, Dinwiddie County, Takeoff Minimums and Obstacle DP, Amtd 1
Burlington, WI, Burlington Muni, RNAV (GPS) RWY 11, Orig-C
Burlington, WI, Burlington Muni, RNAV (GPS) RWY 29, Amtd 1C
Park Falls, WI, Park Falls Muni, NDB RWY 36, Amtd 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, Amtd 15D
Rescinded: On February 7, 2019 (84 FR 2441), the FAA published an Amendment in Docket No. 31229, Ammd No. 3831, to Part 97 of the Federal Aviation Regulations under section 97.33. The following entry for College Station, TX, effective February 19, 2019, is hereby rescinded in its entirety:
College Station, TX, Easterwood Field, RNAV (GPS) RWY 29, Amtd 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, 301–766–3944, 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(i)(1)). We refer to these devices as “postmarket 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
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>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation.</td>
</tr>
<tr>
<td>Infection</td>
<td>Reprocessing validation and Labeling.</td>
</tr>
<tr>
<td>Intraoral/temporomandibular joint injury, irritation, or pain due to:</td>
<td>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.</td>
</tr>
<tr>
<td>• Use error</td>
<td>Human factors assessment and Labeling.</td>
</tr>
<tr>
<td>• Algorithm-directed positioning</td>
<td>Labeling.</td>
</tr>
<tr>
<td>• Interface with other devices</td>
<td>Labeling.</td>
</tr>
<tr>
<td>• Device electrical failure</td>
<td></td>
</tr>
<tr>
<td>Incorrect titration level due to use error</td>
<td></td>
</tr>
<tr>
<td>Disruption of sleep</td>
<td></td>
</tr>
<tr>
<td>Temporary change in bite or dentition</td>
<td></td>
</tr>
</tbody>
</table>

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

§ 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.


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


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.

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I. Background

II. Response to Comment

III. Final Action

IV. Incorporation by Reference

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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).