is codifying the classification of the
device by adding 21 CFR 882.5893. We
have named the generic type of device
thermal vestibular stimulator for head
ache, and it is identified as a
prescription device used to stimulate
the vestibular system by applying
thermal waveforms through earpieces
placed in a patient’s ear canal for the
treatment of headache.

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, Cleaning validation, and Labeling.</td>
</tr>
<tr>
<td>Thermal injury</td>
<td>Labeling, Non-clinical performance testing, Thermal safety testing, Technical specifications, and Software verification, validation, and hazard analysis.</td>
</tr>
<tr>
<td>Ear tenderness and/or pruritus</td>
<td>Labeling, Non-clinical performance testing, Thermal safety testing.</td>
</tr>
<tr>
<td>Nausea and/or dizziness</td>
<td>Labeling, Non-clinical performance testing, and Software verification, validation, and hazard analysis.</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>Labeling, Non-clinical performance testing, and Software verification, validation, and hazard analysis.</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 exempt from the
requirement for adequate directions for
use for the layperson under section
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. 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
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 notification, have been
approved under OMB control number
0910–0231; the collections of
information in 21 CFR part 820,
regarding quality system regulations,
have been approved under OMB control
number 0910–0073; 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 882

Medical devices.

Therefore, under the Federal Food,
Drug, and Cosmetic Act and under
authority delegated to the Commissioner
of Food and Drugs, part 882 is amended
as follows:

PART 882—NEUROLOGICAL DEVICES

§ 882.5903 Thermal vestibular stimulator
for headache.

(a) Identification. The thermal
vestibular stimulator for headache is a
prescription device used to stimulate
the vestibular system by applying
thermal waveforms through earpieces
placed in a patient’s ear canal for the
treatment of headache.

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

1. The authority citation for part 882
continues to read as follows:

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

2. Add § 882.5893 to subpart F to read
as follows:

§ 882.5893 Thermal vestibular stimulator
for headache.

(a) Identification. The thermal
vestibular stimulator for headache is a
prescription device used to stimulate
the vestibular system by applying
thermal waveforms through earpieces
placed in a patient’s ear canal for the
treatment of headache.

(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) Performance testing must validate
electromagnetic compatibility and
electrical, mechanical, and thermal
safety.

(3) The technical parameters of the
device, including waveform outputs and
temperature limits, must be identified.

(4) Cleaning validation of earpieces
must be conducted.

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

(6) Labeling must include the
following:

(i) Information on how the device
operates and the typical sensations
experienced during treatment;

(ii) A detailed summary of the
device’s technical parameters; and

(iii) Instructions for maintenance and
cleaning of the device.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–22842 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P
I. Background

Upon request, FDA has classified the intranasal electrostimulation device for dry eye symptoms as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness in in part by reducing regulatory burdens. 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(f)(1) of the FD&C Act (21 U.S.C. 360c(f)) 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(i)) 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 shall 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 to market a substantially equivalent device (see 21 U.S.C. 360(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 23, 2017, Allergan submitted a request for De Novo classification of the TrueTear Intranasal Tear Neurostimulator. 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. 360(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 May 17, 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 886.5310. We have named the generic type of device intranasal electrostimulation device for dry eye symptoms, and it is identified as a prescription non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms.

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>Tissue damage due to overstimulation/understimulation or mechanical injury (ex: tips too long), device breakage.</td>
<td>Non-clinical performance testing; Software verification, validation, and hazard analysis; Electrical, thermal, and mechanical safety testing; and Labeling.</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).

At the time of classification, intranasal electrostimulation devices for dry eye symptoms 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 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 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 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

§ 886.5310 Intranasal electrostimulation device for dry eye symptoms.

(a) Identification. An intranasal electrostimulation device for dry eye symptoms is a prescription non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms.

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

1. Clinical performance testing must evaluate improvement of dry eye symptoms under anticipated conditions of use.

2. Non-clinical performance testing must assess the following electrical output specifications: waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

3. Patient-contacting components of the device must be demonstrated to be biocompatible.

4. Performance testing must demonstrate the electrical, thermal, and mechanical safety along with electromagnetic compatibility (EMC) of the device in the intended use environment.

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

6. Training for the proper use of the device must be provided.

7. Physician and patient labeling must include:

   (i) Summaries of electrical stimulation parameters;
   (ii) Instructions on how to correctly use and maintain the device;
   (iii) Instructions and explanations of all user-interface components;
   (iv) Information related to electromagnetic compatibility classification;
   (v) Instructions on how to clean the device; and
   (vi) Summaries of clinical performance testing demonstrating safety and effectiveness.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–22785 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P