



May 17, 2018

Allergan  
Nooshin Azizi  
Manager, Regulatory Affairs  
2525 Dupont Drive  
Irvine, California 92612

Re: DEN170086

Trade/Device Name: TrueTear Intranasal Tear Neurostimulator  
Regulation Number: 21 CFR 886.5310  
Regulation Name: Intranasal electrostimulation device for dry eye symptoms  
Regulatory Class: Class II  
Product Code: QBR  
Dated: October 20, 2017  
Received: October 23, 2017

Dear Ms. Azizi:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the TrueTear Intranasal Tear Neurostimulator, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The TrueTear Intranasal Tear Neurostimulator provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the TrueTear Intranasal Tear Neurostimulator, and substantially equivalent devices of this generic type, into Class II under the generic name Intranasal electrostimulation device for dry eye symptoms.

FDA identifies this generic type of device as:

**Intranasal electrostimulation device for dry eye symptoms.** 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On October 23, 2017, FDA received your De Novo requesting classification of the TrueTear Intranasal Tear Neurostimulator. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the TrueTear Intranasal Tear Neurostimulator into class I or II, it is necessary that the proposed class have sufficient regulatory 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 De Novo request, FDA has determined that, for the previously stated indications for use, the TrueTear Intranasal Tear Neurostimulator can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

<b>Identified Risks</b>	<b>Mitigation Measures</b>
Tissue damage due to overstimulation/understimulation or mechanical injury (ex: tips too long), device breakage	Non-clinical performance testing Software verification, validation, and hazard analysis Electrical, thermal, and mechanical safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Infection	Labeling
Electrical shock or burn	Electrical, thermal, and mechanical safety testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling
Pain, headache, or discomfort	Clinical performance testing Non-clinical performance testing Electrical, thermal, and mechanical safety testing

	Labeling
Failure to mitigate dry eye symptoms	Clinical performance testing Training Labeling

In combination with the general controls of the FD&C Act, the Intranasal electrostimulation device for dry eye symptoms is subject to the following special controls:

- (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:
  - a. Summaries of electrical stimulation parameters.
  - b. Instructions on how to correctly use and maintain the device.
  - c. Instructions and explanations of all user-interface components.
  - d. Information related to electromagnetic compatibility classification.
  - e. Instructions on how to clean the device.
  - f. Summaries of clinical performance testing demonstrating safety and effectiveness.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Intranasal electrostimulation device for dry eye symptoms they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Elvin Ng at 301-796-6620.

Sincerely,

Angela Krueger  
Deputy Dir., Engineering and Science Review  
Office of Device Evaluation  
Center for Devices and Radiological Health