May 1, 2020

Olympic Ophthalmics, Inc.
℅ Ms. Janice Hogan
Official Correspondent
Hogan Lovells US LPP
1735 Market St
Philadelphia, PA 19103

Re: DEN190026
Trade/Device Name: iTEAR100 Neurostimulator
Regulation Number: 21 CFR 886.5305
Regulation Name: Electromechanical tear stimulator
Regulatory Class: Class II
Product Code: QKV
Dated: May 15, 2019
Received: May 15, 2019

Dear Ms. Hogan:

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 iTEAR100 Neurostimulator, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The iTEAR100 Neurostimulator is an electromechanical nerve stimulator device, indicated for temporary use (up to 30 days) to increase acute tear production during vibratory stimulation of the external nasal nerve in adults, under prescription of an eye care provider.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the iTEAR100 Neurostimulator, and substantially equivalent devices of this generic type, into Class II under the generic name electromechanical tear stimulator.

FDA identifies this generic type of device as:

> **Electromechanical tear stimulator.** An electromechanical tear stimulator is a non-implantable device intended to increase tear production via mechanical stimulation.

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 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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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 announcing the classification.

On May 15, 2019, FDA received your De Novo requesting classification of the iTEAR100 Neurostimulator. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the iTEAR100 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 iTEAR100 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks	**Mitigation Measures**
Tissue damage due to overstimulation/understimulation or mechanical injury, device breakage	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction	Biocompatibility evaluation 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
Insufficient tear production	Clinical performance testing

In combination with the general controls of the FD&C Act, the electromechanical tear stimulator is subject to the following special controls:

1. Clinical performance testing under anticipated conditions of use must evaluate tear production and all adverse events, including tissue damage, pain, headache, and discomfort.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be conducted:
    a. An assessment of mechanical output specifications including vibration amplitude and frequency, pressure and force, and acoustic (noise level) properties;
    b. Mechanical safety testing to validate safeguards related to the pressure aspects of the device; and
    c. Use life testing.

3. Performance data must demonstrate the electrical safety, thermal safety, and electromagnetic compatibility (EMC) of all electrical components of the device.

4. All patient-contacting components of the device must be demonstrated to be biocompatible.

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

6. Physician and patient labeling must include:
    a. A detailed summary of the device's technical parameters;
    b. Instructions for use, including an explanation of all user-interface components and information regarding proper device placement;
    c. Information related to electromagnetic compatibility classification;
    d. Instructions on how to clean and maintain the device;
    e. A summary of the clinical performance testing conducted with the device;
    f. Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device; and
    g. Information on how the device operates and the typical sensations experienced during treatment.

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 electromechanical tear stimulator 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (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 Leonid Livshitz, Ph.D., at 301-796-6860.

Sincerely,

Denise L. Hampton -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health