DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Oculeve, Inc.
c/o Lee Kramm, M.D., M.S.E.
ClinReg Consulting
733 Bolsana Drive
Laguna Beach, CA 92651

April 24, 2017

Re: DEN160030
Intranasal Tear Neurostimulator
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 886.5300
Regulation Name: Tear Electrostimulation Device
Regulatory Classification: Class II
Product Code: PQJ
Dated: July 5, 2016
Received: July 7, 2016

Dear Dr. Kramm:

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 Intranasal Tear Neurostimulator, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> The Intranasal Tear Neurostimulator provides a temporary increase in tear production during neurostimulation in adult patients.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Intranasal Tear Neurostimulator, and substantially equivalent devices of this generic type, into class II under the generic name, tear electrostimulation device.

FDA identifies this generic type of device as:

> **Tear Electrostimulation Device**. A tear electrostimulation device is a non-implantable, electrostimulation device intended to increase tear production.

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 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 July 7, 2016, FDA received your De Novo requesting classification of the Intranasal Tear Neurostimulator into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the 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 the Intranasal Tear Neurostimulator, indicated for a temporary increase in tear production during neurostimulation in adult patients, 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Tissue damage due to over-stimulation/under-stimulation 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
Pain, headache, or discomfort	• Non-clinical performance testing • Electrical, thermal, and mechanical safety testing • Labeling
Adverse tissue reaction	• Biocompatibility • 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

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

1. 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.

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

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

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

5. 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.

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

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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.

If you have any questions concerning this classification order, please contact LCDR Scott Steffen, Ph.D. at 301-796-6860.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director,
Engineering and Science Review (Acting)
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