March 16, 2022

Olympic Ophthalmics
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K213623
Trade/Device Name: iTEAR100 Neurostimulator
Regulation Number: 21 CFR 886.5305
Regulation Name: Electromechanical Tear Stimulator
Regulatory Class: Class II
Product Code: QKV
Dated: February 7, 2022
Received: February 7, 2022

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K213623

Device Name

iTEAR100 Neurostimulator

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Olympic Ophthalmics, Inc. iTEAR100 Neurostimulator

The assigned 510(k) number is K213623.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Olympic Ophthalmics, Inc.
160 NW Gilman Blvd No. 412
Issaquah, WA 98027
Phone: 650-283-9388
Facsimile: 206-984-1564
Contact Person: Michael Gertner

Date Prepared: November 16, 2021

Device Information

Name of Device: iTEAR100 Neurostimulator

Classification Name: Electromechanical tear stimulator

Regulatory Class: Class II

Product Code: QKV

Regulation: 21 CFR 886.5305

Predicate Device

iTEAR100 Neurostimulator (DEN190026)

Device Description

The iTEAR100 device is a prescription only, non-implantable, electromechanical stimulator intended to increase tear production acutely (over 30 days) through vibratory stimulation of the external nasal nerve in adult patients. The device's technological principle is the application of mechanical vibration to specific sensory neurons on the side of the nose. The device is battery-operated with a single vibratory tip. As the tip is pushed against the tissue, the beam deflects inward until it is deflected fully into the device. The device consists of a handheld unit with a plastic shell, power button, charging port, and effector tip accessible from the exterior. The interior includes mechanical and electrical subsystems comprised of a motor, supercapacitor, printed circuit board assembly (PCBA) including driver board, control board and Bluetooth microprocessor, vibrating cantilever beam attached to the effector tip, and real-time clock.

The iTEAR100 Neurostimulator connects via Bluetooth Low Energy to a mobile application downloaded onto the user's mobile device (compatible with iOS or Android operating system). The mobile application is necessary to activate the device for initial use and collects device usage data which the user may upload to a cloud database at the user's discretion.

Intended Use / 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.

Substantial Equivalence

The iTEAR100 is substantially equivalent to the iTEAR100 previously cleared by FDA under DEN190026. The primary difference between the iTEAR100 and the predicate device is the addition of Bluetooth connectivity, which enables wireless transmission of device usage data and remote activation of the iTEAR100 for use by authorized patients (i.e., users with a prescription). Whereas the predicate device connected to a computer via a cable to transmit usage data, the subject iTEAR100 connects via Bluetooth to a smartphone (iOS or Android platforms) to transmit device usage data wirelessly. And whereas the predicate device was activated for patient use by the manufacturer through a wired connection to a computer before the device was shipped to the patient, the subject iTEAR100 is activated / reactivated after the patient receives the device and has verified their identity and prescription through a mobile application connected to the iTEAR100 via Bluetooth. These modifications did not change the functions of the device but rather changed the ways those functions are performed: wirelessly rather than through wired connections. Furthermore, these changes have no impact on the device's intended use as a tear stimulator. In addition to Bluetooth connectivity, the patient-contacting materials were reduced from both plastic (ABS) and silicone to only plastic (ABS). The material in the subject device is manufactured and processed in the same way as the predicate device. Therefore, these modifications do not raise different questions of safety or effectiveness and the devices are substantially equivalent.

Performance Data

The following test data were submitted in support of substantial equivalence:

- **Biocompatibility** – The iTEAR100 is a surface device with limited (≤ 24 hours) contact with intact skin. In accordance with ISO 10993-1, the following testing was performed:
    - Cytotoxicity (ISO 10993-5),
    - Sensitization (ISO 10993-10),
    - Irritation (ISO 10993-10).

- **Electrical safety and electromagnetic compatibility testing** was performed per IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 62366-1, and ANSI C63.27. These tests were the same as those performed for the predicate device (except the ANSI C63.27:2017 for the Bluetooth communication).

- **Software verification and validation testing** was performed in conformance with IEC 62304 Edition 1.1 2015-06. The subject device software, like the predicate device, presents a "moderate" level of concern.

- **Life testing** was performed to assess the useful life of the iTEAR100. The life testing simulated 12 months of twice-daily, bilateral use.

- **Comparative Testing** – Bench testing was conducted to demonstrate equal performance by the subject device and predicate device in the following mechanical outputs:
    - Frequency
    - Amplitude
    - Acceleration
    - Force-displacement
    - Temperature
    - Noise

Conclusions

The iTEAR100 has the same intended and indications for use and similar technological characteristics and principles of operation as the predicate device. The minor technological differences between the iTEAR100 and its predicate device raise no new or different questions of safety or effectiveness. Performance data demonstrate that the iTEAR100 is as safe and effective as the iTEAR100. Therefore, the iTEAR100 is substantially equivalent.

Substantial Equivalence Table

	iTEAR100 Neurostimulator (Subject Device) (K213623)	iTEAR100 Neurostimulator (Predicate Device) (DEN190026)	Comparison
Classification	21 CFR 886.5305 (product code QKV)	21 CFR 886.5305 (product code QKV)	Same
Intended Use	Increase tear production via mechanical stimulation.	Increase tear production via mechanical stimulation.	Same
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.	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.	Same
User Population	Adults	Adults	Same
Key Technological Characteristics	• Cantilever • Weighted Motor • Maximum input to motor using step up • PCBA with motor control, data logging, wireless communication (Bluetooth) • Mobile app • Cloud database	• Cantilever • Weighted Motor • Maximum input to motor using step up • PCBA with motor control, data logging, wired communication (USB)	Change from wired communication to Bluetooth communication and the addition of a mobile app and cloud database do not raise different questions of safety or effectiveness.
Accessories	Charge cord, protective pouch	Charge cord, protective pouch	Same
Dimensions (l x w x h)	80 mm x 58 mm x 25 mm	80 mm x 58 mm x 23.5 mm	Similar
Effector Tip thickness	2.9 mm	2.9 mm	Same
Tip Protrusion from housing (no load)	5.1 mm	5.0 mm	Similar
Power Source	3.7 V rechargeable battery	3.7 V rechargeable battery	Same
Frequency	200 – 300 Hz (270 unloaded)	200 – 300 Hz (270 unloaded)	Same
Amplitude	< 1.0 mm	< 1.0 mm	Same

	iTEAR100 Neurostimulator (Subject Device) (KXXXXXX)	iTEAR100 Neurostimulator (Predicate Device) (DEN190026)	Comparison
Safety Features	Tip retraction (< 6.0 N) Vibration damping at 2 mm Disable device after 30 days of use Prescription and user verification required prior to device activation	Tip retraction (< 6.0 N) Vibration damping at 2 mm Disable device after 30 days of use Prescription required prior to device activation	The prescription and user verification processes in the subject device are additional safety features that do not raise different questions.
Materials / Biocompatibility	ABS Lustran 348 (housing, cantilever, power button)	ABS Lustran 348 (housing, cantilever), Silicone (power button)	All materials used in the subject device, including the ABS are the same as the materials used in the predicate. The power button is now made from the same materials as the housing and cantilever and therefore no longer needs to be coated in silicone.
Key Software Functions	Secure prescription activation, firmware to control voltage to battery, on-off, data logging, power level indication, disable device after 30 days of use	Firmware to control voltage to battery, on-off, data logging, power level indication, disable device after 30 days of use	The subject device secure prescription activation is an additional safety feature that does not raise new questions.
Data Transfer	Wireless (Bluetooth Low Energy)	Wired (USB)	The difference does not raise different questions of safety or effectiveness.
Sterilization	Non-sterile	Non-Sterile	Same
Charging Port	USB-C	Micro-USB	The difference in charging connectors does not affect device safety or effectiveness.
Use Life	6 months	6 months	Same
Memory	EEPROM	SD Card	The difference in memory does not affect device safety or effectiveness.