August 31, 2020

Allergan
Barbara Simon
Director, Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92612

Re: K193589
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: July 29, 2020
Received: July 30, 2020

Dear Barbara Simon:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193589

Device Name
TrueTear Intranasal Tear Neurostimulator

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

I. APPLICANT:	Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 Phone: (714) 246-4500 Fax: (714) 796-3015
Contact:	Barbara Simon Director, Regulatory Affairs Allergan, Inc. (714) 246-4393
Date Summary Prepared:	April 17, 2020

II. DEVICE

Trade Name:	TrueTear Intranasal Tear Neurostimulator
Classification Name:	Intranasal electrostimulation device for dry eye symptoms (21 CFR 886.5310)
Device Class:	Class II
Device Product Code:	QBR

III. PREDICATE DEVICE

Allergan TrueTear Intranasal Tear Neurostimulator (DEN170086)

IV. DEVICE DESCRIPTION

The TrueTear device is a prescription only, non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms. The device's technological principle is the application of low-level electrical stimulation to sensory neurons located in the nose to acutely increase tear production and improve dry eye symptoms. The device consists of three distinct non-sterile subassemblies – a base unit which controls and produces electrical stimulation waveform and enables the patient to control the neurostimulation, a disposable tip that is inserted into the nose and provides the contact surface for the stimulation to the target tissue located in the nose, and a charger case that protects the device and replenishes the sealed battery inside the base unit between uses.

The disposable tip connects to the base unit and provides the contact for conducting low-level electrical stimulation current, which is produced by the base unit, to the target site on the inside of the nose.

The device includes a wireless communications module and is capable of providing basic communication over a Bluetooth Low Energy (BLE) channel and a radio frequency identification (RFID) transceiver. The wireless module does not allow control or modification of the base unit that produces the stimulation. The BLE channel is a one-way, outbound-only channel that allows patients to view summary device use data on an optional mobile app. The RFID channel is used to authenticate that the disposable tip is genuine, untampered and allows the base unit to indicate when the tip is due for disposal.

V. 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.

The Indications for Use statement is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The predicate device is the previous version of the TrueTear Intranasal Tear Neurostimulator that was described in de novo DEN170086. The predicate device and the subject device have the same technological principle: the use of low-level electrical stimulation to sensory neurons located in the nose to acutely increase tear production and improve dry eye symptoms. At a high level, the subject and predicate devices are based on the following same technological elements:

- A base unit that controls and produces electrical stimulation waveform and enables the patient to control the neurostimulation
- A disposable tip that is inserted into the nose to reach target tissue located inside the nose and provides the contact surface for the stimulation
- A charger that replenishes the sealed battery inside the base unit
- A wireless BLE communication module that allows one-way summary device use data to be viewed by the patient on an optional mobile app

The following technological differences exist between the subject and predicate devices:

- Addition of RFID transceiver to the base unit
- Addition of RFID tag embedded in the tip body, a non-tissue contact portion of the tip and not visible to the patient

- Use of stainless steel 316 instead of a proprietary hydrogel as the stimulation contact surface of the tip
- Consolidation of the charger and cover into a charging case; and updated base unit and charger dimensions to provide a more modern look and feel
- Labeling modifications to reflect updated technological changes and the material change for the surface contact in the disposable tip; updated instructions to dispose of used tips within 28 days of first use versus disposal of used tips daily

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Electrical Output Specifications

Within the demonstration of substantial equivalence, performance testing for assessing the electrical outputs was conducted. The testing evaluated the output 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. The performance results met the intended electrical output design specifications, which remain unchanged from the predicate device.

Biocompatibility

Biocompatibility evaluation was performed according to ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The disposable tip is classified per ISO 10993-1 as a surface device with long-term mucosal membrane contact. The stainless steel 316 electrode used in the subject device conforms to ASTM MIM-316L. The subject device meets the biocompatibility requirements and complies with ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-18:2005.

Electrical Safety Electromagnetic Compatibility (EMC)

Performance testing for electrical, thermal, and mechanical safety and EMC for the subject device and intended use environment (home use) was performed. The subject device complies with IEC 60601-1-2 (Edition 4.0):2014, IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012, IEC 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2012 (Third Edition) + A1:2012, and IEC 60601-2-10: 2012 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition)+A1:2012.

Software

Software verification and validation testing was performed and complies with IEC 62304:2006 + A1:2015 (2015-06). The subject device software has been assigned a "moderate" level of concern, which is unchanged from the predicate device.

Wireless Communications

Cybersecurity and coexistence evaluations were performed for the wireless communication module modifications. The subject device has appropriate mitigations for cybersecurity and coexistence testing confirmed that the device's essential performance is not affected by near range devices and data can be transmitted in the presence of active RF energy sources.

Other Performance Data

Electrical and mechanical performance bench testing was evaluated for the disposable tip for the intended use duration of 28 days to confirm the subject device disposable tip met specified design criteria. The performance test results met the design specifications. Additionally, performance testing was conducted for the disposable tips to evaluate worst-case conditions for electrical stimulation durability and for durability during insertion and cleaning to demonstrate that the tips maintained electrical and mechanical integrity throughout their maximum usage period. The worst-case performance test results met the design specifications.

Animal Studies

The design modifications did not require animal studies to demonstrate substantial equivalence.

Clinical Studies

The design modifications did not require clinical testing to demonstrate substantial equivalence.

VIII. CONCLUSION

The objective evidence presented in the de novo submission for the predicate device demonstrated the clinical safety and effectiveness of the TrueTear Intranasal Tear Neurostimulator. The modified device relies on the same technological principle as the predicate device, and the modifications do not raise different questions of safety and effectiveness. The predicate and subject devices have the same intended use. The non-clinical performance evaluations demonstrate that the subject device performs comparably to the predicate device in the same use conditions. The changes that have been made to the device's overall design, hardware and software do not affect the intended use or risk profile of the device. Therefore the subject device described in this submission is substantially equivalent to the predicate device.