June 3, 2022

Oasis Medical, Inc
Ting-Hsuan Wu
Regulatory Affairs Specialist
514 S Vermont Avenue
Glendora, CA 91741

Re: K213988
Trade/Device Name: SOFT PLUG Extended Duration 180 Tapered Canalicular Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: April 15, 2022
Received: April 20, 2022

Dear Ting-Hsuan Wu:

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)*
K213988

Device Name

SOFT PLUG Extended Duration 180 Tapered Canalicular Plug

Indications for Use *(Describe)*

The SOFT PLUG Extended Duration 180 Canalicular Plugs and the SOFT PLUG Extended Duration 180 Tapered Canalicular Plugs are intended to temporarily block tear flow by the occlusion of the canaliculus in order to:

- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye,
- Temporarily treat dry eye after ocular surgery, and
- Determine the potential effectiveness of permanent occlusion.

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.

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510(k) SUMMARY

Applicant's Name and Address:	OASIS Medical, Inc. 514 S. Vermont Ave. Glendora, CA 91741
Contact Person:	James Christensen Director Research and Development (626) 852-5156
Date Prepared:	May 24, 2022
510(k) Number:	K213988
Device Trade Name:	SOFT PLUG® Extended Duration 180 Tapered Canalicular Plug
Common Name:	Intracanalicular Plug
Regulation Name:	Plug, Punctum
Regulatory Class:	Unclassified
Product Code:	LZU
FDA Panel:	Ophthalmic
Basis for Submission:	Traditional 510(k): Device modification
Predicate Device:	K162361 SOFT PLUG® Extended Duration 180 Canalicular Plug
Device Description Summary:	The Oasis Medical SOFT PLUG® Extended Duration 180 Tapered Canalicular Plug is a mid-term duration device designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system for approximately 180 days. The plugs are made from degradable polydioxanone monofilament colored violet with D&C No. 2. The plugs are 2.0mm long and have a base diameter of 0.6mm with one end tapered to enable easier placement through the punctal opening.
Indications For Use:	The SOFT PLUG® Extended Duration 180 Canalicular Plugs and the SOFT PLUG® Extended Duration 180 Tapered Canalicular Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to: - Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases, - Temporarily enhance the efficacy of topical medications or ocular lubricants, - Temporarily treat contact lens intolerance secondary to dry eye, - Temporarily treat dry eye after ocular surgery, and - Determine the potential effectiveness of permanent occlusion.

Summary of Technology Characteristics:	There are no differences in the material used for this device and the predicate device. Both devices are formed from polydioxanone monofilament which is a polymerized composition of *p*-dioxanone monomer and D&C Violet Number 2 dye. There are differences in the geometry of this devise compared to the predicate device. Both style plugs are 2.0mm long. The tapered style plug has a base diameter of 0.6mm with one end of the plug tapered and the other end flat. The predicate device is a cylindrical style plug having a range of diameters from 0.3mm to 0.5mm with both ends of the plug flat. Both style plugs are designed to be inserted through the punctal opening and reside in the canaliculus until they degrade. The angle of the tapered end of the tapered style plug approximates the angle of a punctal dilator, a device used to enlarge the punctal opening to ease insertion of a plug. There are no differences in the function of these devices. No additional questions of safety and effectiveness are raised due to material, design, or function.
Summary of Non-clinical Testing:	Biocompatibility testing from the predicate device premarket 510(k) submission K162361, SOFT PLUG® Extended Duration 180 Canalicular Plug, is leveraged as applicable for this device. Cytotoxicity testing performed in accordance with ISO 10993-5 supports that the manufacturing process to form the tapered end of the plug does not affect the toxicology of the device compared to the predicate device Accelerated *in-vitro* degradation studies in accordance with ASTM F1635 supports that the manufacturing process to form the tapered end of the plug does not affect the degradation rate of the device compared to the predicate device A shipping study performed in accordance with ISO 11607, ASTM D4169 and ISTA 2A supports that the packaging is suitable for use and the sterile barrier is not affected by the revised product design.
Substantial Equivalence Basis:	The conclusions drawn from non-clinical performance tests demonstrate that the SOFT PLUG® Extended Duration 180 Tapered Canalicular Plug is as safe and effective as the predicate device, and is substantially equivalent to the predicate device.