DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2017

Oasis Medical, Inc.
% James Christensen
New Product Development
514 S. Vermont Avenue
Glendora, CA 91741

Re: K162361
Trade/Device Name: Soft Plug® Extended Duration 180 Canalicular Plug
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LZU
Dated: March 6, 2017
Received: March 10, 2017

Dear James Christensen:

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. 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); 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 Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162361

Device Name
Soft Plug® Extended Duration 180 Canalicular Plug

Indications for Use *(Describe)*
Indications for Use:

The Soft Plug® Extended Duration 180 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.

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.***

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Food and Drug Administration
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*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."*

## 5. 510(k) SUMMARY

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| Applicant's Name and Address: | OASIS Medical, Inc.<br>514 S. Vermont Ave.<br>Glendora, CA 91741 |
| Contact Person: | James Christensen<br>New Product Development<br>(626) 852-5156 |
| Date Prepared: | March 6, 2017 |
| Device Trade Name: | SOFT PLUG® Extended Duration 180 Canalicular Plug |
| Common Name: | Intracanalicular Plug |
| Regulation Number: | Unclassified |
| Regulation Name: | Plug, Punctum |
| Regulatory Class: | Unclassified |
| Product Code: | LZU |
| FDA Panel: | Ophthalmic |
| Predicate Device: | K150288 – PDO Absorbable Punctal Plug |
| Device Description Summary: | The OASIS Medical SOFT PLUG® Extended Duration 180 Canalicular Plug is a mid-term implant 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 absorbable polydioxanone monofilament colored violet with D&C No. 2. The plugs are 2.0mm long and available in 0.2mm, 0.3mm, 0.4mm, and 0.5mm diameters. |
| Indications For Use: | The SOFT PLUG® Extended Duration 180 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. |

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| Summary of Technology Characteristics: | There are no differences in the material used for these devices. The plugs are cut from polydioxanone monofilament which is a polymerized composition of *p*-dioxanone monomer and D&C Violet Number 2 dye.<br><br>There are no differences in the design of these devices. The plugs are 2.0mm long. The plugs are available in four diameters: 0.2mm, 0.3mm, 0.4mm, and 0.5mm which are based on USP synthetic absorbable suture diameters.<br><br>The plugs are designed to be inserted through the punctal opening and reside in the canaliculus until these are absorbed.<br><br>There are no differences in the function of these devices.<br><br>No additional questions of safety and effectiveness are raised due to material, design, or function. |
| Summary of Non-clinical Testing: | Accelerated shelf life testing conducted on ethylene oxide sterilized product showed an average loss of tensile strength of 9% across all plug diameters after two years equivalent storage in foil pouches. A loss of 20% in tensile strength represents an approximate 10-15% shortening of the 120-180 day absorption period in the body.<br><br>Chemical characterization and biocompatibility testing were performed in accordance with ISO 10993-18:2005 and ISO 10993-1:2009. Based on a toxicological risk assessment, the likely exposure level of all compounds found are present at levels that can be considered safe and acceptable.<br><br>A Product Adoption Study performed in accordance with ANSI/AAMI/ISO 11135:2014 was performed to adopt the product into the Product Family currently sterilized by a validated ethylene oxide cycle. Ethylene oxide residuals have been reduced below the levels of concern in accordance with ISO 10993-7:2008.<br><br>Bacterial endotoxin testing conducted on similar plug products manufactured, packaged and sterilized in a similar manner, has been shown to be below 20 EU/device in accordance with USP <85> in 39-NF34:2016.<br><br>A shipping study was performed in accordance with ISO 11607:2016, ASTM D4169-13 and ISTA 2A 2011. There was some damage to the corrugated outer case and minor damage to some of the chipboard cartons, but there was no damage to the pouched product or loss of plugs from their foam holders. |

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| Substantial Equivalence Basis: | The conclusions drawn from non-clinical performance tests demonstrate that the SOFT PLUG® Extended Duration 180 Canalicular Plug is as safe and effective as the predicate device, and is substantially equivalent to the predicate device. |