October 24, 2019

AlphaMed, Inc.
Mr. James Gubachy
VP - Quality Assurance
3912 Mountain Ave
El Paso, TX 79930

Re: K190210
Trade/Device Name: Tear Pool Dissolvable Punctum Plugs
Regulatory Class: Unclassified
Product Code: LZU
Dated: September 25, 2019
Received: September 26, 2019

Dear Mr. Gubachy:

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)*
K190210

Device Name
Tear Pool Dissolvable Punctum Plugs

Indications for Use *(Describe)*
Tear Pool Dissolvable Punctum Plugs are designed to provide for temporary occlusion of the tear drainage system.

Punctum Plugs are indicated for:
* As a diagnostic aid to determine the potential effectiveness of long term occlusion
* To temporarily enhance the efficacy of topical medications or ocular lubricants
* After ocular surgery to prevent complications due to dry eyes
* To evaluate treatment of ocular dryness
* To evaluate the dry eye component of ocular surface diseases

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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Submitter's Name:	AlphaMed Inc.
Submitter's Address:	3912 Mountain Ave El Paso, TX 79930
Submitter's Telephone:	915-595-2020
Submitter's Contact:	James Gubachy 915-595-2020 jgubachy@alphamedco.com
Date 510 (k) Summary Prepared:	October 24, 2019
Device Trade Name:	Tear Pool Dissolvable Punctum Plugs
Device Common Name:	Punctum Plug
Classification Name:	Unclassified
Product Code:	LZU
Predicate Device:	Dissolvable Opaque Herrick Lacrimal Plug
Predicate Device 510(k) No.:	K030300

Description of Device

The Tear Pool Dissolvable Punctum Plug is an ophthalmic device commonly referred to as a punctum plug. It is designed to be inserted by a practitioner into the canaliculus to temporarily restrict the natural lubricating tears from draining off the surface of the eye.

This treatment is prescribed for temporary occlusion in the treatment of certain eye conditions collectively referred to as dry eye disease, as well as the dry eye component of ocular surface diseases and other conditions of tear insufficiency.

Tear Pool Dissolvable Punctum Plugs are cylindrical in shape. Approximately 2.0mm in length and are available in two sizes: 0.4mm and 0.5mm. Each plug is composed of polydioxanone(PDO). The plug is dyed with an approved color additive, D & C Violet No. 2.

A Tear Pool Dissolvable Punctum Plug is mounted on a specially designed insertion tool and placed into a plastic tray then sealed with a Tyvek® cover. The primary package is sent to the sterilizer for Ethylene Oxide sterilization. Two sterile trays, one IFU, two chart labels and one silica gel packet are sealed in a pouch and placed in a shelf box.

Device Description (continued)

The Pre-Loaded Tear Pool Dissolvable Punctum Plugs are available in the following models and diameters and are 2.0mm in length

Model# 20-5304	0.4mm
Model# 20-5305	0.5mm

The device is make from Polydioxanone(PDO). The plugs are violet in color.

Differences: The Tear Pool Dissolvable Punctum Plug and the Predicate Device are identical except the Tear Pool Dissolvable Punctum Plug uses an insertion tool. The results of performance testing on the insertion tool and biocompatibility studies with the addition of an insertion tool demonstrate that it does not impact the safety and effectiveness of the Device.

Indications for Use: Tear Pool Dissolvable Punctum Plugs are designed to provide for temporary occlusion of the tear drainage system.

Punctum Plugs are indicated for:

* As a diagnostic aid to determine the potential effectiveness of long term occlusion
* To temporarily enhance the efficacy of topical medications or ocular lubricants
* After ocular surgery to prevent complications due to dry eyes
* To evaluate treatment of ocular dryness
* To evaluate the dry eye component of ocular surface diseases

Differences: There is no content difference between the Indication for Use for the Predicated Device and the Tear Pool Dissolvable Punctum Plug.

Technological Characteristics

The Tear Pool Dissolvable Punctum Plug has the same design as the Predicate Device. Both devices are made with Polydioxanone(PDO).

Neither the Tear Pool Dissolvable Punctum Plug nor the Predicate Device us software or an energy source, contain biologics or drugs, and do not use coatings or additives.

Differences: There are no technological differences.

Performance Data

Non-clinical performance data includes biocompatiblity testing, sterilization validation, insertion tool testing, package validation and environment of use.

Biocompatibility Testing:

L929 Neutral Red Uptake Test per ISO 10993-5 Biological Evaluatio of Medical Devices - Part 5: Tests for *In Vitro* Cytotoxicity.

The requirements of the standard were met. .

Performance Data (continued)

Kligman Maximization Test per ISO 10993-10, 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
The requirements of the standard were met.

Intracutaneous Injection Test per ISO 10993-10, 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
The requirements of the standard were met.

Physicochemical Test for Plastic Material of Construction - Polycarbonate per United States Pharmacopoeia 42, National Formulary 37, 2019, <661.1> Plastic Materials of Construction - Polycarbonate.
The requirements of the standard were met.

Results of Biocompatibility Studies indicate that the Pre-Loaded Tear Pool Dissolvable Punctum Plug is a safe device.

Sterilization:

Ethylene Oxide Sterilization Validation per ISO 11135: 2014 Sterilization of Health Care Products - Ethylene Oxide-Part 1: Requirement for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.
The requirements of the standard were met

EO Residual per ISO 10993-7: 2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
The requirements of the standard were met.

Bacterial Endotoxin Test per USP 41, Chapter <85> & ANSI/AAMI ST72:2011 Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing.
The requirements of the standard were met.

Pre-Loaded Tear Pool Dissolvable Punctum Plugs and the Predicate Device use the same sterilization method: Ethylene Oxide

Insertion Tool:

The performance of the insertion tool was assessed using a Simulated Use Deployment Test in gel to verify that the plug is not damaged and that it is retained and delivered easily by the user. To test the reliability of the pre-loaded insertion tool, multiple deployments were performed.

The insertion tool performs as intended.

Performance Data (continued)

Packaging:
A Tear Pool Dissolvable Punctum Plug is mounted onto an insertion tool and sealed in a tray with a Tyvek® sterile barrier lid. Final packaging includes two sterile trays (two plugs), one instructions for use, one silica gel packet, vacuum sealed in a pouch then placed in a shelf box.

Environment of Use:
Tear Pool Dissolvable Punctum Plugs and the Predicate Device are for professional use only.

Conclusions:

The proposed Device has the same design, performance and safety profile as that of the Predicate Device and is therefore Substantially Equivalent.