DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2016

Lacrimedics, Inc.
Ms. Rebecca Cyd Dutton
Regulatory and Compliance Officer
2620 Williamson Place NW, Suite 113
DuPont, WA 98327

Re: K161673
Trade/Device Name: LacriPro Punctum Plug
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LZU
Dated: September 28, 2016
Received: October 11, 2016

Dear Ms. Dutton:

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,

Kesia Alexander

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)*
K161673

Device Name

LacriPro Punctum Plug

Indications for Use *(Describe)*

LacriPro plugs may be used to:

- Treat Dry Eye Syndrome
- Treat ocular dryness secondary to contact lens use
- Enhance the efficacy of topical ocular medications
- Prevent complications due to dry eyes after surgery
- Treat 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.**

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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*"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**
**LacriPro® Punctum Plugs**

| | |
|---|---|
| **Submitter's Name:** | Lacrimedics, Inc. |
| **Submitter's Address:** | 2620 Williamson Place NW<br>Suite 113<br>DuPont, WA 98327 |
| **Submitter's Telephone/Fax:** | 253-964-0360 / 253-964-2699 |
| **Submitter's Contact:** | Rebecca Cyd Dutton<br>360-376-7900<br>rdutton@lacrimedics.com |
| **Date 510 (k) Summary Prepared:** | January 13, 2016 |
| **Device Trade Name:** | LacriPro® Punctum Plugs |
| **Device Common Name:** | Punctum Plug |
| **Classification Name:** | Punctum Plug |
| **Product Code:** | LZU |
| **Predicate Device:** | AquaFlo Punctum Plugs |
| **Predicate Device 510(k) No.:** | K021936 |

**Description of Device**

The proposed device is an ophthalmic device commonly referred to as a punctum plug. It is designed to be placed by a practitioner into the punctal opening (upper/lower) to restrict the natural lubricating tears from being pumped off the surface of the eye.

This treatment is prescribed for long-term 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.

LacriPro Punctum Plugs have a distal tip, a proximal cap and a body (tubular shaft) connecting the tip to the cap. The cap is designed to rest on the opening of the puncta after the tip and body are inserted into the canalicular canal. The cap has one or more recesses (depending on diameter) for retaining tear fluid.

The plug has a passage extending in the distal direction from an opening in the proximal cap to facilitate mounting on an insertion tool.

## Device Description (continued)

The LacriPro Punctum Plugs are available in the following models, diameters and lengths:

| | |
|---|---|
| Model # 1833 | 0.6mm (1.42mm length) x-small |
| Model # 1835 | 0.7mm (1.52mm length) Small |
| Model # 1837 | 0.8mm (1.60mm length) Medium |
| Model # 1839 | 0.9mm (1.78mm length) Large |

The device is made from silicone liquid rubber MED 4870 by Nusil, Inc. The plugs are clear, or translucent.

## Indications for Use

LacriPro plugs may be used to:

- Treat Dry Eye Syndrome
- Treat ocular dryness secondary to contact lens use
- Enhance the efficacy of topical ocular medications
- Prevent complications due to dry eyes after surgery
- Treat the Dry Eye component of ocular surface diseases

The Indications for Use for the LacriPro Punctum Plug are similar to the Indications for Use for the Predicate Device. Enhancing efficacy of topical ocular medications and prevention of complications due to dry eyes after surgery have been included in the indications for LacriPro, but are not included in the predicate device indications. There is sufficient clinical evidence to support the use of punctum plugs after surgery, as well as enhancing the efficacy of topical ocular medications. The predicate device includes treating allergies as an indication; this treatment was not included in the indications for use for the LacriPro due to a lack of sufficient clinical evidence.

## Technological Characteristics

The proposed device has the same design as the Predicate Device. Both devices are made with medical grade silicone, Nusil, Inc. MED 4870.

Neither the Predicate device or the proposed device use software or an energy source, contain biologics or drugs, and do not use coatings or additives.

Both devices are molded using injection molding.

**Differences:** There are no technological differences.

## Performance Data

Non-clinical performance data includes sterilization validation, package integrity testing, and biocompatibility studies.

*Sterilization:* AquaFlo and LacriPro use the same sterilization method: $VD_{max}25$ Gamma Sterilization.

*Environment of Use:* LacriPro Punctum Plugs and the predicate device are for professional use only.

## Performance Data (continued)

*Packaging:* Molded plugs are mounted onto an insertion tool and sealed in a tray with a Tyvek® lid barrier prior to sterilization. A Package Integrity Study was performed using a five-year accelerated aging study and a five-year real time aging study. The tray seals were challenged using the Burst Test method and a sterility test was performed on both the accelerated and real time aging samples. A Shipping and Handling Study was performed to support the seal of the pouch up to five years under normal shipping and handling conditions.

*Biocompatibility Testing:* Results of Biocompatibility Studies indicate LacriPro Punctum Plug is a safe device.

## Conclusions

The proposed device has the same design, performance and safety profile as that of the Predicate Device and is therefore substantially equivalent.