July 24, 2019

Omnivision AG
% Oliver Eikenberg, PhD
Senior Consultant, QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K182984
Trade/Device Name: MaxiTears CONTACTS PF
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC, LPN
Dated: June 14, 2019
Received: June 17, 2019

Dear Dr. Eikenberg:

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)*
K182984

Device Name
MaxiTears® CONTACTS PF

Indications for Use *(Describe)*
MaxiTears® CONTACTS PF eye drops have been formulated for use with both soft and rigid gas permeable (RGP) contact lenses, to rewet lenses before insertion and lubricate lenses during wear. It also relieves minor irritation, discomfort, dryness, blurring and itchiness, which may occur while wearing your lenses.

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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510(k) Summary

MaxiTears CONTACTS PF

K182984

1. **Submission Sponsor**

Omnivision AG
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Switzerland
Contact: Joachim Kolter, Management Representative (QMB)

2. **Submission Correspondent**

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Contact: Oliver Eikenberg, PhD
Title: Senior Consultant, Quality & Regulatory Affairs

3. **Date Prepared**

07/16/2019

4. **Device Identification**

Trade/Proprietary Name:	MaxiTears™ CONTACTS PF
Common/Usual Name:	Lens Care products
Classification Name:	Rigid Gas Permeable (RGP) Contact Lens Care Products Soft (hydrophilic) Contact Lens Care Products
Regulation Number:	§886.5918 , §886.5928
Product Code:	MRC, LPN
Device Class:	Class II
Classification Panel:	Ophthalmic

5. Legally Marketed Predicate Device(s)

PREDICATE: K032030, *blink*™ CL Lubricant Eye Drops, manufactured by Advanced Medical Optics, CA, USA

6. Indication for Use Statement

MaxiTears® CONTACTS PF eye drops have been formulated for use with both soft and rigid gas permeable (RGP) contact lenses, to rewet lenses before insertion and lubricate lenses during wear. It also relieves minor irritation, discomfort, dryness, blurring and itchiness, which may occur while wearing your lenses.

7. Device Description

The **MaxiTears® CONTACTS PF** are ready-to-use, isotonic, sterile eye contact lens care products (lubricants) intended to moisturize and lubricate the lens drops in eyes to reduce minor symptoms of dry eyes such as burning or itching. The intended use of these contact lens rewetting and lubricating solutions is to alleviate the symptoms of dryness, discomfort, and minor irritation caused by ocular fatigue induced by the wearing of contact lenses, for example, by environmental conditions (dust, smoke, dry heat, air conditioning, wind, cold) tiredness or extended extended computer screen use. The **MaxiTears CONTACTS PF** solution can be used with all types of contact lenses, except contact lenses manufactured from Efrofilcon A, and are intended for repeated use over an extended period of time.

The **MaxiTears CONTACTS PF** solution it to be introduced to the US-market as an Over the Counter (OTC) medical device similar to other 510k-cleared lens drop lubricants (and identical to predicate Blink CL Lubricant Eye Drops K032030), sold as OTC medical device in retail outlets and through the internet.

OmniVision AG is offering the **MaxiTears CONTACTS PF** solution as Over the Counter device:

- **MaxiTears® CONTACTS PF** is a medium viscous preservative-free solution packaged in single-use ampoules (single-dose units - SDU). They are supplied as single-dose unit plastic ampoules designed to administer one drop and then to be discarded. They are indicated for users with a known history of allergy to preservatives and those who wear contact lenses.

8. Substantial Equivalence Discussion

The following table compares the "**MaxiTears® CONTACTS PF**" to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject devices do not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

	Subject Device	Predicate Device	Device Comparison
Manufacturer	**Omnivision AG (SWITZERLAND)**	**Advanced Medical Optics, (USA)**	
Trade Name	**MaxiTears® CONTACTS PF**	***blink™* CL Lubricant Eye Drops**	
510(k) Number	K182984	K032030	*NA*
Product Code	MRC, LPN	MRC, LPN	*Same*
Regulation Number	21 CFR 886.5918 Rigid Gas Permeable (RGP) Contact Lens Care Products 21 CFR 886.5928 Soft (hydrophilic) Contact Lens Care Products		*Same*
Regulation Panel	Ophthalmic		*Same*
Principle of Operation	Physical mode, Works inside of the eye providing moisturization and lubrication for Soft & RGP Contact Lenses		*Same*
Over the Counter Use	Yes	Yes	*Same*
Multi or Single-Use	Single-use variants	Multi-use only	*Similar*
Variants	MaxiTears® CONTACTS PF	blink™C L Lubricant Eye Drops	*Similar, different packaging*
Indications for Use	MaxiTears® CONTACTS PF eye drops have been formulated for use with both soft and rigid gas permeable (RGP) contact lenses, to rewet lenses before insertion and lubricate lenses during wear. It also relieves minor irritation, discomfort, dryness, blurring and itchiness, which may occur while wearing your lenses.	Use **blink™** CL Lubricant Eye Drops to lubricate and rewet soft and rigid gas permeable (RGP) contact lenses; to help relieve dryness, irritation and discomfort that may be associated with lens wear; and to cushion lenses by placing a drop on the lens prior to application on the eye.	*Similar, the indications for use are both for eye lubricant on soft and rigid gas permeable lenses*
Clinical Indication	Relief of symptoms of eye dryness and irritation due to environmental conditions of the eye caused by Contact Lenses		*Same*
Volume / Bottle	5x, 20x or 60x 0.4 mL , single-use vials	2 mL (0.06 fl oz), multi-use 10 mL (0.34 fl oz) multi-use	*Similar*
Overall Design	Sterile, Buffered, Isotonic, Aqueous Solution	Sterile, Buffered, Isotonic, Preserved Aqueous Solution	*Similar*
Appearance	Clear, colorless solution packaged in single-use plastic vials (single dose units)	Clear, colorless solution packaged in plastic bottles with controlled dropper tips	*Same*
Active ingredients	No	No	*Same*
Preserved	No	OcuPure (Oxychloro Complex 0.005 %)	*NA*
Humectant	Sodium hyaluronate	Sodium hyaluronate	*Same*
Osmolality	270-330 mosmol/kg	267 mosmol/kg	*Similar*
Buffered	Yes, pH 6.8-7.6	Yes, pH 7.2	*Similar*
Sterile	Yes, aseptic filling	Yes, aseptic filling	*Same*
Shelf Life	2 years	> 9 month 45 days after opening	*Similar*
Biocompatibility	Yes, ISO 10993 series	Yes, ISO 10993 series	*Same*

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of **MaxiTears CONTACTS PF** and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Omnivision AG completed a number of non-clinical performance tests. The **MaxiTears CONTACTS PF** meets all the requirements for overall design, sterilization and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

The **MaxiTears CONTACTS PF** passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility evaluation and biocompatibility testing of **MaxiTears CONTACTS PF** lens drop solutions for patient-contacting materials including chemical characterization, genotoxicity, cytotoxicity, sensitization and irritation reactivity, subacute and systemic toxicity per ISO 10993-1, 3, 5, 10, 11, 12, 17, 18 ; PASSED all testing

- Cleaning and Sterilization Testing – **MaxiTears CONTACTS PF** lens drop solutions are not sterilized in their final packaging. The sterile bulk solution is stored under aseptic conditions within the storage tank and then for the filling process pushed through a sterile polypropylene filter 1.2µm to the sterilized blow-fill-machine under sterile nitrogen pressure. The sterility of the final solution is preserved by an overpressure sterile nitrogen flow. The filling is performed into natural plastic pellets, made of transparent LDPE, which were extruded at temperatures between 160 and 190 °C. The molds which leave the extruder, immediately transformed into the 0.4ml Single Dose Unit (SDU)-blocks for **MaxiTears CONTACTS PF**. The blown SDU are sterile due to the high temperature applied. The devices are classified as Established Category A per the FDA Guidance *"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile"*. Sterility tests are performed according USP39-NF34 <71>; PASSED all testing

- In vitro lens compatibility testing - testing demonstrates physical product compatibility from **MaxiTears CONTACTS PF** lens care solutions with both soft (hydrophilic) and RGP contact lenses according ISO 1198 and ISO 18369-2, -3; PASSED all testing

- Shelf Life Testing – shelf life determination is based on real time as well as open vial (in-use) stability studies of the **MaxiTears CONTACTS PF** lens drop solutions performed in compliance with ICH guidance document Q1A and with ISO 13212:2014 Ophthalmic optics -- Contact lens care products -- Guidelines for determination of shelf-life; PASSED all testing

- Storage and Transport Testing include transport validation under routine conditions with different lots of manufactured **MaxiTears CONTACTS PF** assembled in different packaging variants to maintain integrity through normal shipping and handling; PASSED all testing

- Usability engineering testing per IEC 62366; PASSED all testing

- Risk Management per ISO 14971 and EN ISO 14971; all requirements were met and risks reduced as far as possible.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. This type of device, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the **MaxiTears® CONTACTS PF** and the predicate device **blink™ CL Lubricant Eye Drops** does not raise any questions regarding its safety and effectiveness. Technological product characteristics, performance testing and compliance with voluntary standards, demonstrate that the **MaxiTears® CONTACTS PF** are substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, performance characteristics, and intended use.

The **MaxiTears CONTACTS PF**, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.