September 18, 2020

Optixon Inc.
% Eunbae Cho
General Manager
IGC Co., Ltd.
Rm. 501, Daeryung techno town 7th, #638,
Seobusaet-gil, Geumcheon-gu
Seoul, Republic of Korea 08504

Re: K201013
Trade/Device Name: Optixon 1-Day
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 13, 2020
Received: August 17, 2020

Dear Eunbae Cho:

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)*
K201013

Device Name
OPTIXON 1- DAY

Indications for Use *(Describe)*
OPTIXON 1- DAY are indicated for single-use, disposable daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity.

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

Preparation Date: Sep 10, 2020

A.510k Number: K201013

B. Applicant: Company name: OPTIXON Inc

Address: 105/106 ho, 164, Obong-ro, Buk-Gu, Daegu, Rep. of Korea

C. Proprietary and Established Names: OPTIXON Inc
Address: 105/106 ho, 164, Obong-ro, Buk-Gu, Daegu, Rep. of Korea

D. Regulatory Information

- Classification Name: lenses, soft contact, daily wear
- Common / Usual Name: Soft (hydrophilic) contact lens
- Proprietary Name: OPTIXON 1- DAY
- Classification / Product Code: Class 2 / LPL (21 CFR 886.5925)

E. Indications for Use

OPT IXON 1- DAY are indicated for single-use, disposable daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity.

F. Description

OPTIXON 1- DAY (omafilcon A)is daily disposable soft contact lenses(single use) produced from the HEMA-MPC copolymer material. MPC is similar to phospholipids (e.g., phosphatidylcholine)

The contact lenses contain 59% water by weight and is sold in the blister package immersed in packaging saline. RB 246 pigment conforms to 21 CFR Part 73.3106 is used to provide the handling blue tint for the lens.

The device is a corneal contact lens having a total diameter more than the visible iris diameter and is designed to be worn in its entirety on the cornea. The device has an aspheric front curve (external curve) which is tri-curve and spherical base curve (internal curve).

The contact lenses are hydrophilic, soft and it is supplied in sterile state.

G. Substantial Equivalence Information

-Predicate Device-1
SE Number: K162223
Product name: Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses
Company: Supervision Optimax Sdn Bhd

-Predicate Device-2
SE Number: K 112302
Product name: Proclear lens
Company: CooperVision, Inc.

Manufacturer	OPTIXON Inc	*Supervision Optimax Sdn Bhd*	*CooperVision, Inc*
Device name	OPTIXON 1-DAY	*Aveo (omafilcon A) 1-DAY Aspheric Soft (Hydrophilic) Contact Lens*	*Proclear (omafilcon A) Soft Contact Lenses*
510(k) No.	-	*K162223*	*K 112302*
Intended Use	OPTIXON 1- DAY are indicated for single-use, disposable daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity.	Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with nondiseased eyes that are myopic or hyperopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity. The contact lenses are intended for daily wear, single use and are to be discarded at the end of the day.	Proclear Asphere omafilcon A) Soft Contact lenses are indicated for daily wear for the correction of visual acuity in nonaphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.
Modality	Daily Wear	Daily Wear	Daily Wear
Material USAN Name	omafilcon A	omafilcon A	omafilcon A
FDA Category (Group)	Group II Non-ionic, High water	Group II Non-ionic, High water	Group II Non-ionic, High water
Manufacturing Method	Cast Molded	Cast Molded	Finished Inside Polymerization System II
Curing	Thermal Cure	Thermal Cure	Thermal Cure

Sterilization	Moist heat sterilization	Moist heat sterilization	Moist heat sterilization
Visibility Tint	Reactive Blue Dye 246	Reactive Blue Dye 246	VAT Blue 6
Water Content	59% ± 2%	59% ± 2%	59% ± 2%
Package Saline	Phosphate Buffered Saline	Phosphate Buffered Saline	Phosphate Buffers PEG200 and Tween 80
Oxygen Permeability (Dk) $x10^{-11}$	25.68	25.68	21.05
Light transmission	98%	98%	>90%
Base Curve	8.4mm to 8.8mm	8.4mm to 8.8mm	8.0mm to 9.3mm
Diameter $Ø_T$	14.0 to 14.4mm	14.0mm to 14.4mm	13.6mm to 15.2mm
Power	-0.50D to - 10.0D	-10.00 to +6.00	-20.00 to +20.00

H. Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Physiochemical Studies
The physiochemical studies were conducted according to ISO 18369-4:2006 Ophthalmic Optics-Contact Lenses-Part 4: Physiochemical properties of contact lens materials and ISO 18369-3:2006 Ophthalmic Optic-Contact Lenses-Part 3: Measurement methods. The physical, optical and chemical properties of the lens are within established specifications for the lenses.

Toxicology Studies
Toxicology (in-vivo and in-vitro) studies reports show that the lenses are non-toxic and biocompatible with the ocular environment.

Cytotoxicity test	According to EN ISO 10993- 5 :2009	Passed
Skin sensitization test	According to EN ISO 10993-10 :2010	Passed
Ocular irritation test	According to EN ISO 10993-10 :2010	Passed
Acute Systemic Toxicity	According to ISO 10993-11 : 2017	Passed

I. Clinical Test
The technological characteristics, formulation, manufacturing and sterilization processes are the same as the predicate device Aveo (omafilcon A) 1-DAY Aspheric Soft (Hydrophilic) Contact Lens K162223 and Proclear (omafilcon A) Soft Contact Lenses K 112302. Therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

J. **Conclusion**
OPTIXON 1-DAY is substantially equivalent to the predicate device, Aveo (omafilcon A) 1-DAY Aspheric Soft (Hydrophilic) Contact Lens K162223 and Proclear (omafilcon A) Soft Contact Lenses K 112302 in term of optical property, Physiochemical and pre-clinical toxicology. They

are produced from the same material (omafilcon A), have the same functional and scientific technology, lens characteristics and the intended use is identical. It is concluded that the lenses are as safe, as effective and perform as well as the predicate devices.