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

May 17, 2016

Smart Performer Corp. Ltd.
Mr. Jeffersion Shen
QA Dept. Manager & Management Representative
No.13-1, Wuquan 1st Rd., Xinzhuang Dist.
New Taipei City, 242 TW

Re: K152657
Trade/Device Name: Smart Performer 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 8, 2016
Received: April 8, 2016

Dear Mr. Shen:

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

Indications for Use Statement

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)*

K152657

Device Name
SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*

SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is intended to use as correction of refractive myopia in aphakic or non-aphakic persons with non-diseased eyes, who may have 1.00D of astigmatism or less. The lenses are available with a visibility-handling tint or with a decorative tint intended to enhance or alter the apparent color of the eye.

Eyecare practitioners may prescribe the contact lens for single-use disposable daily wear. The SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lenses are not intended to be disinfected and should be discarded after a single use.

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

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR 807.92.

The assigned 510(k) number is K152657 .

Submitter Information

Company	SMART PERFORMER CORP. LTD. No.13-1, Wuquan 1st Rd., Xinzhuang Dist., New Taipei City 242, Taiwan (R.O.C.)
Contact Person	Jeffersion Shen QA Dept. Manager & Management Representative
Telephone	886-2-22999699
Fax	886-2-22996866
E mail	jeffersion@smartvision.tw
Date of Summary	July 8, 2015

Device Information

Name of Device	SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens
Common Name	Soft (hydrophilic) contact lens, daily wear
Classification	Class II
Regulation Number	886.5925
Product Code	LPL, MVN
Review Panel	Ophthalmic Devices

Predicate Device

- iLens@ (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens, K141280, submitted by SEINOH OPTICAL CO. LTD. .
- BIOMEDICS UV Colors (Ocufilcon D) Soft (hydrophilic) Contact Lens, K013377, submitted by Ocular Sciences Inc.
- ACUVUE 2 *COLOURS* Brand (etafilcon A) Contact Lens with UV blocker, K010114, submitted by VISTAKON, Division of Johnson & Johnson Vision Care, Inc.

Intended Use

SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is intended to use as correction of refractive myopia in aphakic or non-aphakic persons with non-diseased eyes, who may have 1.00D of astigmatism or less. The lenses are available with a visibility-handling tint or with a decorative tint intended to enhance or alter the apparent color of the eye.
Eyecare practitioners may prescribe the contact lens for single-use disposable daily wear. The SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lenses are not intended to be disinfected and should be discarded after a single use.

Device Description

The SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is available as spherical lenses manufactured by cast molded method. The lens is made from a lens material that is approximately 55% water. The hydrogel lens' material is a copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with ethyleneglycol dimethacrylate (EGDMA) via UV photo-polymerization.
The SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is available visibility tinted and cosmetic tinted. The visibility tinted lens is tinted blue using Reactive Blue Dye #19 to make the lenses more visible for handling. The cosmetically tinted lens is tinted in an annular pattern, providing a clear optic zone, with iron oxides (red) or C.I. Pigment green 7. The cosmetically tinted lens is available in GREEN and RED. The lens is supplied sterile in sealed blister packers containing sterile isotonic phosphate buffered saline.

The Lens designs in the following parameter ranges:

Chord Diameter	13.8 mm to 14.8 mm
Center Thickness	0.060 mm to 0.250 mm (varies with power)
Base Cure	8.2 mm to 9.0 mm
Power	-0.25D to -12.00 D

The Lens designs in the following physical properties:

Refractive Index	1.41
Water Content	55 %
Oxygen Permeability (Dk)*	23 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C (revised Coulometric method)
Light Transmittance	＞97% (clear) ＞97% (tinted)
Specific Gravity	1.10 (hydrated)

Non-Clinical Studies

The following tests were conducted as recommended by the Premarket Notification 510 (k) Guidance Document for Daily Wear Contact Lenses, revised May 1994.

(a). Biocompatibility (cytotoxicity, ocular irritation, delayed type hypersensitization and acute systemic injection)

(b). Physicochemical Testing

(c). Stability Testing

Clinical Studies

Ocufilcon D lenses have been used widely. Their safety and effectiveness have been well documented. Their safety and effectiveness can be further exemplified by two lenses cleared by FDA

- iLens@ (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens, K141280
- BIOMEDICS UV Colors (Ocufilcon D) Soft (hydrophilic) Contact Lens, K013377

Clinical studies for SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens are not required for premarket notification as the USAN name and process are the same as the above mentioned predicate devices.

Substantial Equivalence Summary

Information submitted in the 510(k) establishes that the SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens has comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Results of cytotoxicity, ocular irritation, delayed type hypersensitization and acute systemic injection showed the SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate devices in safety and biocompatibility. Therefore, the SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate devices.

Substantial Equivalence Comparison				
Device	SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens	iLens@ (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens	BIOMEDICS UV Colors (Ocufilcon D) Soft (hydrophilic) Contact Lens	ACUVUE 2 COLOURS Brand (etafilcon A) Contact Lens with UV blocker
Material (USAN name)	Ocufilcon D	Ocufilcon D	Ocufilcon D	Etafilcon A
Indication for use	correction of refractive ametropia	correction of refractive ametropia	correction of refractive ametropia	correction of refractive ametropia
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded	Cast Molded
Water Content	55%	55%	55%	58%
Light Transmittance	＞97%	＞95%	＞97 %	＞70%
Dk (35 ℃)	23×10^{-11}	20×10^{-11}	19.6×10^{-11}	21.4×10^{-11}
Refractive Index	1.41	1.405	1.41	1.40
Toxicity	Non-Toxic	Non-Toxic	Non-Toxic	Non-Toxic
Color Additives	• Iron oxides (red) • C.I. Pigment green 7	Reactive blue dye #19	• Iron oxides • Titanium Dioxide • Carbazole Violet • Copper Phthalocyanine Blue • Copper Phthalocyanine Green	• iron oxides • titanium dioxide • Reactive blue dye 4 • Vat orange 1 • Phthalocyanine Green • Phthalocyaninato(2-) cooper

Conclusion

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens and to establish substantial equivalence to the predicate devices. Information submitted in the 510(k) also establishes that the lens do not raise questions of safety and effectiveness. Therefore, the SMART PERFORMER 55 (Ocufilcon D) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate devices.