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

August 10, 2015

Yung Sheng Optical Co., Ltd.
Mr. Wen-Han Chen
RA Supervisor
3f-1, No. 6, Jhongke Road, Daya District
Taichung City, TW 42881

Re: K151586
Trade/Device Name: Eye Secret 55 UV Aspheric (methafilcon A) 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: June 9, 2015
Received: June 11, 2015

Dear Mr. Chen:

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 801and Part 809); 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 and Part 809), 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 Y. Alexander -A

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.*

51O(k) Number *(if known)*

K151586

Device Name

Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye.

The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

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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"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

1. **Type of Submission:** Traditional 510(k)

2. **Submitter:** Yung Sheng Optical Co., Ltd.
Address: 3F-1, No.6, Jhongke Road, Daya District, Taichung City 42881 Taiwan
Manufacturing facility: No.8, Keya 2nd Road, Daya District, Taichung City 42881, Taiwan
Phone: (04) 25658384 #156、191
Fax: (04) 25658387
Contact: Wen-Han Chen / Che-Yu Shen
Date prepared: May 29, 2015
Establishment Registration Number: 3004021238

3. **Identification of the Device**

Proprietary/Trade name:	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens
Common Name:	Contact Lens
Classification Name:	Lenses, Soft Contact, Daily Wear
Device Classification:	II
Regulation Number:	886.5925
Panel:	Ophthalmic
Product Code:	LPL for Lenses, Soft Contact, Daily Wear MVN for Lens, Contact, (Disposable)

4. **Identification of the Predicate Device**

Predicate Device Name:	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens
Manufacturer:	Yung Sheng Optical Co., Ltd.
510(k) Number or Clearance Information:	K133735

5. Intended Use and Indications for Use of the subject device

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye.

The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

6. Device Description

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is manufactured by using cast molding method. The lens material, Methafilcon A, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) and Methacrylic acid (MAA) crosslinked with ethylene glycol dimethacrylate (EGDMA). A UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280 to 315 nm and less than 50% in the UVA range of 316 to 380 nm. The lenses are tinted blue for visibility purposes with the color additives, C.I. Reactive Blue No.4.

The lenses are available as aspheric lenses. Each finished lens is supplied in a plastic blister container with a sterile isotonic phosphate buffered saline solution containing sodium hyaluronate and trehalose wetting agents.

7. Summary of Clinical Study

Methafilcon A lenses have been used widely. Their safety and effectiveness have been well documented and cleared by FDA “Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens (K133735)” submitted by Yung Sheng Optical Co., Ltd. is an example.

Clinical study for the subject device is not required for the premarket notification as the USAN name and process are the same as the above mentioned predicate device.

8. Non-Clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens. The results of all testing demonstrated that the safety and effectiveness of the subject device are equivalent to the predicate device, Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens (K133735). The following tests were conducted as recommended by the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, 1994:

- Toxicity
  1. Acute Systemic Injection Study: The lens material meets the requirements of the systemic injection test and is considered non-toxic.
  2. White Rabbit Ocular Irritation Test: Ocular irritation test was performed and produced no ocular irritation.
  3. Cytotoxicity Test: The test article meets the requirements of ISO 10993-5.
- Extractables (Leachability)
- Finished Lens Parameters
- Light Transmittance
- Refractive Index
- Water Content
- Shelf-life
- Mechanical Properties Comparative Testing
- Physical Compatibility Test with Contact Lens Care Solution and Packaging Solution

The results of the non-clinical testing demonstrated that the Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate device.

9. Substantial Equivalence Determination

The information presented in this submission establishes the substantial equivalence of the subject device "Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens" to the predicate device. The following table summarized the substantial equivalence comparison information.

	Subject Device	K133735
Device Name	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens
Intended Use	The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye. The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.	The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact lenses are indicated for the correction of ametropia (myopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from 0.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. Eye Care professionals may prescribe the lens for daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.
Material	Methafilcon A	Methafilcon A
Manufacturing Method	Cast Molded	Cast Molded
Water Content	55 %	55 %

Device Name	Subject Device	K133735
	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens	Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens
Powers	-0.50 D ~ -20.00 D	-0.00 ~ -12.00 D
Light Transmittance	95 % (± 5 %)	95 % (± 5 %)
UV-A	< 50 %	< 50 %
UV-B	< 5 %	< 5 %
Refractive Index	1.409 (± 0.005 n_d)	1.409 (± 0.005 n_d)
Base Curve	7.85 ~ 10.00 (± 0.20 mm)	8.60 (± 0.20 mm)
Diameter	12.00 ~ 15.00 (± 0.20 mm)	14.20 (± 0.20 mm)
Tint	C.I. Reactive Blue #4 for handling purpose	C.I. Reactive Blue #4 for handling purpose
Packaging solution	Phosphate buffered saline solution containing sodium hyaluronate and trehalose.	Phosphate buffered saline solution.

10. Conclusion

After analyzing the bench tests and safety testing data, it can be concluded that the Eye Secret 55 UV Aspheric (Methafilcon A) Soft (hydrophilic) Contact Lens is substantially equivalent to the predicate device.