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

October 30, 2014

Unilens Corp., USA
Mr. Alan J. Frazer
Director of Quality Assurance
10431 72nd Street, North
Largo, FL 33777

Re: K142851
Trade/Device Name: C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic)
Regulation Number: 21 CFR 886.5925
Regulation Name: Lenses, soft contact, daily wear
Regulatory Class: Class II
Product Code: LPL
Dated: September 29, 2014
Received: September 30, 2014

Dear Mr. Frazer:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 -S

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)*
K142851

Device Name
CVUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with nondiseased eyes. The lens may be worn by persons who require up to 3.00 Diopters of add and who exhibit astigmatism of up to 0.75 Diopters that does not interfere with visual acuity.

The CVUE ADVANCED (hioxifilcon D) Toric and Multifocal Toric Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.00 diopters in aphakic and/or notaphakic persons with non-diseased eyes.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

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.

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# 510(k) Summary

## Applicant Information

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|---|---|
| Date prepared: | 17 Sep 2014 |
| Name: | Unilens Corp., USA |
| Address: | 10431 72nd Street, North<br>Largo, FL 33777 |
| Contact person: | Alan J. Frazer<br>Director of Quality Assurance |
| Phone number: | (727) 544-2531 |
| Fax number: | (727) 545-1883 |

## Device Information

| | |
|---|---|
| Device classification: | Class II |
| Classification number: | LPL |
| Classification name: | Lenses, Soft Contact, Daily Wear |
| Trade name: | C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens |

## Equivalent device

The C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate device identified below in terms of intended use.

Predicate devices:

LifeStyle MV2 Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear

C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

## Device description

CVUE ADVANCED (hioxifilcon D) soft contact lenses are semi-scleral flexible shells which cover the cornea and may cover a portion of the adjacent sclera and are available as aspheric single vision, multifocal, toric, or toric multifocal designs. Torics have a toroidal posterior optic zone, and multifocals have the most plus power is in the center of the lens, with the power progressively becoming more minus towards the periphery. Torics have the option of dynamic axis stabilization (double slab off) or prism ballast stabilization. All lenses share a base curve with a flattened peripheral curve which approximates the curvature of the sclera. The lens material, (hioxifilcon D), is a non-ionic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2, 3-dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% hioxifilcon D

and 54% water by weight when immersed in normal buffered saline solution. The lens is available with or without a blue visibility handling tint, phthalocyanato (2) -(copper).

The CVUE ADVANCED (hioxifilcon D) soft contact lens is a hemispherical shell of the following dimensions:

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| Chord diameter: | 12.5 to 17.0mm |
| Center thickness: | 0.13 to 0.73; varies with power |
| Base curve: | 7.0 to 10.5mm |
| Powers: | -20.00 to +20.00 diopters |
| ADD powers (multifocal): | Up to +3.00 diopters |
| Cylinder (toric): | Up to 4.00 diopters |
| Axis (toric): | 0º to 180º in 1º steps |
| Axis stabilization (toric): | prism ballast; or<br>dynamic (double slab off) |
| Optical zone diameters: | 5.0 to 10.0mm |

The physical/optical properties of the lens are:

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| Refractive Index | 1.408 (hydrated) |
| Light Transmission – tinted | greater than 90% |
| Water Content | 54% |
| Specific Gravity | 1.299 (dry) |
| Oxygen Permeability (Dk Value) | 23 x $10^{-11}$ Fatt Units (cm2/sec) (ml O2/ml x mm Hg @ 35°C), ANSI Z80.20:2004 upgraded polarographic method corrected for boundary-layer and edge effects |

Intended Use (Indications)

The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes. The lens may be worn by persons who require up to 3.00 Diopters of add and who exhibit astigmatism of up to 0.75 Diopters that does not interfere with visual acuity.

The CVUE ADVANCED (hioxifilcon D) Toric and Multifocal Toric Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.00 diopters in aphakic and/or not-aphakic persons with non-diseased eyes.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

## Substantial equivalence

The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses will be manufactured according using the specified process controls and the quality management system currently in place. The device will undergo manufacturing, packaging and sterilization procedures that are the same as devices currently manufactured, marketed and distributed by Unilens Corp., USA.

The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device the same to the CVUE ADVANCED (hioxifilcon D), 510(k) K082853.

The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses indications for use do not change

Physical construction and safety and effectiveness do not change from the predicate devices.

This meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise any new or different questions of safety and effectiveness than the predicate devices identified above.