OCT 5 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K121652

Applicant information:

Date Prepared:	1 June 2012
Name:	Unilens Corp., USA
Address:	10431 72nd Street North Largo, FL 33777
Contact person:	Alan J. Frazer Director of Quality Assurance Official Correspondent
Telephone:	727-544-2531

Device information

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear

Equivalent Devices:

The CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear are substantially equivalent to the following predicate devices:

IntelliWave^3, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)
By Art Optical Contact Lens, Inc.
510(k) number K100221

Metro Soft Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)
By Metro Optics of Austin Inc.
510(k) number K100244

CVue Advanced Definitive Daily Wear Soft Contact Lens (efrofilcon A)
By Unilens Corp., USA
510(k) number K100456

Device Description:

The CVue Advanced HydraVUE (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear are fabricated from efrofilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (efrofilcon A) is a daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers and optionally incorporates D&C Green 6 as an integrated handling tint. The lenses are lathe-cut and made to order for individual prescriptions. Each lens consists of 26% efrofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efrofilcon A) name has been adopted by the United States Adopted Names Council (USAN). The blanks from which the lenses are lathe-cut are manufactured by Contamac, Ltd., Bearwalden Business Park, Saffron Walden, Essex CB11 4JX, United Kingdom, UK.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (efrofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The Physical properties of the lens are:

Refractive Index	1.38
Light Transmission	Greater than 97%
Surface Character	Hydrophilic
Water Content	74%
Specific Gravity	1.048 (hydrated)
Oxygen Permeability	59.8 x 10-11(cm/sec) (ml O2/ml x hPa @ 35 °C), (revised Fatt method)

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight. The lenses will be manufactured in spherical, toric, multifocal, multifocal toric and irregular cornea configurations with the following features and properties.

Chord Diameter	12.0 mm to 16.00 mm
Center Thickness	0.01 mm to 0.50 mm
Base Curve	8.0 mm to 9.5 mm
Power Range	-20.00D to +20.00D in 0.25D steps
Cylinder Power (Toric)	-0.25D to -10.00D
Add Power (Multifocal)	+0.50D to +4.00D

The lens is supplied sterile in vials containing a buffered saline solution. Vial labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

Intended Use:

The CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned

replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system or hydrogen peroxide disinfection systems.

Testing:

Non-clinical Testing

Preclinical toxicology and biocompatibility were previously established and are not required for this 510(k). All non-clinical testing was conducted according to valid scientific protocols and was presented in K100456. The pre-clinical data for the contact lens blank material is included in K100456 by reference to the efrofilcon A material in Master File MAF #1708.

Test results of the non-clinical testing on the CVue Advanced HydraVUE (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear demonstrate that:

- Lenses supplied in glass vials are sterile for the indicated shelf-life,
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data

The clinical performance of the efrofilcon A lens material has been previously established, and therefore is not required for this 510(k). The clinical data for the irregular cornea indications is included in K100456 by reference to the efrofilcon A material in Master File MAF #1708.

The CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear are identical to the cleared Intelliwave^3 Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) for irregular cornea management, cleared under K100221, and to the Metro Soft Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) for irregular cornea management cleared under K100244.

The CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear have the identical manufacturing process (lathe cut versus lathe cut) to the cleared Intelliwave^3 Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) for irregular cornea management, cleared under K100221, and to the Metro Soft Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) for irregular cornea management cleared under K100244.

Substantial Equivalence:

The following matrix illustrates the production method, lens function and material characteristics of the CVue Advanced HydraVUE (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lenses for daily wear as well as the predicate devices.

	CVue Advanced HydraVue (efrofilcon A) Irregular Cornea New indication	Art Optical IntelliWave^3 Irregular Cornea (efrofilcon A) Predicate device	Metro Soft irregular cornea (efrofilcon A) Predicate device	CVue Advanced HydraVue Toric Multifocal (efrofilcon A) Predicate device
Intended Use	Indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia, posses refractive astigmatism and/or are presbyopic.
Functionability	Same as predicate device: The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Indications	Daily wear, Silicone Hydrogel Soft (hydrophilic) Contact Lens	Daily wear, Silicone Hydrogel Soft (hydrophilic) Contact Lens	Daily wear, Silicone Hydrogel Soft (hydrophilic) Contact Lens	Daily wear, Silicone Hydrogel Soft (hydrophilic) Contact Lens
Production Method	Lathe-cut, made to order for individual prescriptions	Lathe-cut, custom manufactured	Lathe-cut, custom manufactured	Lathe-cut, custom manufactured
USAN name	efrofilcon A	efrofilcon A	efrofilcon A	efrofilcon A
Water content	74%	74%	74%	74%
Oxygen Permeability	60×10^{-11} (cm^2/sec(ml O_2/ml x mm Hg@35 °C) (revised Fatt method)	60×10^{-11} (cm^2/sec(ml O_2/ml x mm Hg@35 °C) (revised Fatt method)	60×10^{-11} (cm^2/sec(ml O_2/ml x mm Hg@35 °C) (revised Fatt method)	60×10^{-11} (cm^2/sec(ml O_2/ml x mm Hg@35 °C) (revised Fatt method)
Specific Gravity	1.139	1.139	1.139	1.139

Conclusions Drawn from the Studies

Validity of the Scientific Data

As previously presented in predicate 510(k)s, the toxicology studies, microbiology and chemistry studies all followed scientific protocols. The shelf-life stability studies followed scientific protocols, and the data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the CVue Advanced HydraVUE (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel contact lens for daily wear is as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of silicone hydrogel, daily wear soft contact lenses. The benefits to the patient are the same as those for other silicone hydrogel contact lenses when compared to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

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

Re: K121652
Trade/Device Name: CVue Advanced HydraVUE (efrofilcon A) soft (hydrophilic) silicone hydrogel contact lens for dailywear
Regulation Number: 21 CFR 886.5925
Regulation Name: Lenses, Soft Contact, Daily Wear
Regulatory Class: Class II
Product Code: LPL
Dated: September 14, 2012
Received: September 18, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121652

Device Name: CVue® Advanced™ HydraVUE (efrofilcon A) soft (hydrophilic) contact lenses

Indications for Use:

The CVue Advanced HydraVUE Irregular Cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

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 (not heat) lens care system or hydrogen peroxide disinfection system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121652