CooperVision

4. Device Description

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The Proclear *(omafilcon A)* are Daily Wear soft contact lenses intended for single use daily disposable wear or Scheduled Replacement wear. The Proclear *(omafilcon A)* Soft (hydrophilic) contact lenses are a hemispherical shell. The Proclear lens is available in several designs. Spherical or aspherical soft contact lens; Toric is a back surface toric; Multifocal has multiple curves with complementary reverse geometry (N and D) which allows for correction of presbyopia in persons who are myopic or hyperopic; Multifocal Toric has an aspheric front surface with anterior having two multifocal zones with a toric generated surface for the purpose of correcting vision in an eye that is astigmatic. The *omafilcon A* lens material is equivalent to other omafilcon A daily wear hydrophilic contact lenses cleared under several 510(k) notifications. Omafilcon A is composed of polymer of 2-hydroxy-ethylmethacylate and 2-metacryloloyoxyethyl phosphorylcholine cross linked with ethylmethacrylate. The lenses are tinted from edge to edge for visibility purposes with the color additive Vat Blue 6. The physical properties and available dimensions follow:

Chord Diameter	13.0 mm to 15.5 mm
Central Zone Diameter	1.7 mm to 2.6 mm
Center Thickness	0.035 mm to 0.96 mm (varies with power and lens design)
Base Curve	8.00 mm to 9.50 mm
Power Range	-20.00 D to +20.00 D
Add power range	+0.25D to +5.00D as applicable
Cylinder Power	-0.50 D to -10.00D as applicable
Axis	Axis 1° to 180° as applicable
Refractive Index	1.40
Water Content	60% ± 2%
Oxygen Permeability	
Polarographic Fatt Method	21×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)
Modified Fatt Method Guard Ring Edge corrected	25×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35° C. as measured by 201T Permeometer connected to a polarographic cell.
Light Transmittance	>90%

5. Intended Use

Proclear XC and Proclear 1 day

Sphere and Aspheric: (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic 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.

Toric: (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who have astigmatism of 5.00D or less.

Multifocal: (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in not

aphakic persons with non-diseased eyes. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

Multifocal Toric: (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic, possess astigmatism of 10.00 diopters or less, and are presbyopic.

Proclear XC and Proclear 1 Day (*omafilcon A*) Soft (hydrophilic) Contact lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned replacement the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR

When prescribed for Daily Disposable Wear the lens is to be discarded after each removal.

6. Predicate Device(s)

Predicate Device Materials

omafilcon A:
Proclear Daily Wear (*Omafilcon A*) Soft Contact Lenses (K952152)
Proclear Compatibles Daily Wear Contact Lens (*Omafilcon A*) Soft Contact Lenses (K970095)
Proclear and Proclear Compatibles (*Omafilcon A*) Soft Contact Lenses (K974408)

VAT Blue 6 (tint):
Biomedics 52 1-Day (ocufilcon B) UV Blocking Daily Wear Soft (hydrophilic) Contact Lens (K020389)

Predicate Device Lens Designs and Indications for Use

Proclear Compatibles Daily Wear (*Omafilcon A*) Soft Contact Lenses (K970095)
Proclear Compatibles Multifocal (*Omafilcon A*) Soft Contact Lenses (K032873)
Proclear Multifocal (*Omafilcon A*), Proclear Toric (*Omafilcon A*) and Proclear Multifocal Toric (*Omafilcon A*) Soft) Soft Contact Lenses (K050717)
Biomedics 52 1-Day (ocufilcon B) UV Blocking Daily Wear Soft (hydrophilic) Contact Lens (K020389)

7. Characteristics of Substantial Equivalence

MATERIAL COMPARISON TABLE

Reference	**SUBJECT DEVICE** Proclear Aspheric, Proclear Toric, Proclear Multifocal, Proclear Multifocal Toric	**PREDICATE DEVICE** K970095 K974408	**PREDICATE DEVICE** K952152 K974408	**PREDICATE DEVICE** K020389
Material USAN Name	Omafilcon A	Omafilcon A	Omafilcon A	Ocufilcon B
FDA Category (Group)	Group II Non-Ionic High Water Content	Group II Non-Ionic High Water Content	Group II Non-Ionic High Water Content	Group IV Ionic High Water Content
Manufacturing method	Cast Molded	Cast Molded	Lathe-Cut	Cast Molded
Sterilization	Steam: validated autoclave	Steam: validated autoclave	Steam: validated autoclave	Steam: validated autoclave
Packaging	Blister Pack	Blister Pack	Vial	Blister Pack
Labeled Water Content (Thermogravimetric method)	60%	62%	59%	52%
Visibility Tint	Vat Blue 6	C.I Reactive Blue 4	Clear	Vat Blue 6
Color Process	Entrapment	Reactive	No tint	Entrapment

LENS DESIGN AND INDICATIONS FOR USE COMPARISON TABLE
No change to established spherical, asphere, toric, multifocal or multifocal toric lens designs.

	SUBJECT DEVICE	**PREDICATE DEVICE** K032873
Lens Design	Multifocal	Multifocal
Intended use	Correction of Visual acuity in patients with myopia or hyperopia and are presbyopic	Correction of Visual acuity in patients with myopia or hyperopia and are presbyopic
	SUBJECT DEVICE	**PREDICATE DEVICE** K050717
Lens Design	Multifocal Toric	Multifocal Toric
Intended use	Correction of Visual acuity in patients with myopia or hyperopia and are astigmatic and presbyopic	Correction of Visual acuity in patients with myopia or hyperopia and are astigmatic and presbyopic
	SUBJECT DEVICE	**PREDICATE DEVICE** K970095
Lens Design	Sphere, Asphere	Sphere
Intended use	Correction of Visual acuity in patients with myopia or hyperopia	Correction of Visual acuity in patients with myopia or hyperopia
	SUBJECT DEVICE	**PREDICATE DEVICE** K050717
Lens Design	Toric	Toric
Intended use	Correction of Visual acuity in patients with myopia or hyperopia and are astigmatic.	Correction of Visual acuity in patients with myopia or hyperopia and are astigmatic.
	SUBJECT DEVICE	**PREDICATE DEVICE** K020389
Indication	Daily Disposable	Daily Disposable
Intended use	When prescribed for Daily Disposable Wear the lens is to be discarded after each removal.	When prescribed for Daily Disposable Wear the lens is to be discarded after each removal.

8. Physiochemical Studies

Results from physical, optical and chemical properties show substantial equivalency with the predicate devices, and are within established specifications for the lenses.

9. Toxicology Studies

Results from in-vivo and in-vitro studies were conducted and verify that lenses remain non-toxic and biocompatible with the ocular environment.

10. Clinical Studies

The technical characteristics, formulation, manufacturing, and sterilization processes of this lens are equivalent to omafilcon A soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

11. Conclusions

Based on evaluation of material, manufacturing methods, lens parameters and indicated use, the omafilcon A soft contact lens described in this document is substantially equivalent with the predicate devices. Evaluation of chemical/physical properties, biocompatibility and stability studies, confirm the lenses are within established finished product specifications, remain stable, and are non-toxic and biocompatible with the ocular environment and the lens is shown to be safe for its indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CooperVision, Inc.
c/o Lisa Hahn
Global Regulatory Affairs Director
1215 Boissevain Ave.
Norfolk, VA 23507

NOV 22 2006

Re: K061948
Trade/Device Name: Proclear® XC (omafilcon A) and Proclear® 1 day (omafilcon A) Hydrophilic Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: MVN, LPL
Dated: November 17, 2006
Received: November 20, 2006

Dear Ms. Hahn:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

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

510(k) Number (if known): K061948

Device Name: Proclear XC
Proclear 1 day

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

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

510(k) Number K061948