SEP 2 9 2008

K081865

CooperVision® | SEE BEYOND THE ORDINARY™

510(k) Summary

510(k) SUMMARY

1. **Applicant Name & Address:** CooperVision, Inc.
   711 North Road
   Scottsville, NY 14546

2. **Contact:** Bonnie Tsymbal
   Telephone (585) 264-3210
   Facsimile (585) 889-5688

3. **Date Prepared:** June 17, 2008

4. **Device Identification:**

   - Trade Name: Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses
     Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses
     Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses
   - Common Name: Soft Contact Lenses
   - Classification Name: Lenses, Soft Contact, Daily Wear
   - Device Classification: Class II (21 CFR 886.5925)
   - Product Code: LPL

5. **Intended Use:**

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

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The 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).

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic; possess astigmatism of 10.00 diopters or less. The 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 the eye care practitioner in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they

are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

6. **Device Description**

Proclear Toric XR

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lens is a back surface toric. The lenses are made of polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with the color additive Vat Blue 6. Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as astigmatic (toric) lenses with the following dimensions:

- Chord Diameter: 13.6 to 15.2 mm
- Center Thickness 0.09 mm to 0. 65 mm
- Base Curve: 8.0 mm to 9.3 mm
- Spherical Powers: -20.00 D to +20.00 D
- Cylinder Powers: -0.75 to –5.00 D
- Axis 1° to 180°

Proclear Multifocal XR

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as a multifocal lens with an aspherical front surface and spherical back surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. The Proclear Multifocal XR is designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength. The Proclear Multifocal XR / D (dominant) has a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The Proclear Multifocal XR / N (non-dominant) has a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision. The lenses are tinted edge to edge for visibility purposes with the color additive Vat Blue 6.

The lens material, omafilcon A is a copolymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The Proclear UltraVue/D and Proclear UltraVue/N (omafilcon A) Soft (Hydrophilic) Contact Lenses are flexible transparent hemispherical shells of the following dimensions:

- Chord Diameter: 13.6 to 15.2 mm
- Center Thickness (minus): 0.09 mm to 0.65 mm
- Base Curve: 8.3 mm to 8.9mm
- Spherical Powers: -20.00 D to +20.00 D
- Add Powers: +1.00 to +4.00 D
- Central Zone Diameter: 2.3 mm to 2.6 mm (Proclear Multifocal XR / D)
  1.7 mm to 2.0 mm (Proclear Multifocal XR / N)

Proclear Multifocal Toric

510(k) Summary

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are made of polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with the color additive Vat Blue 6.

The front surface of the Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic. The Proclear Multifocal Toric contact lenses are designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

The Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are available in two versions. The ***Proclear Multifocal Toric / D*** with a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The ***Proclear Multifocal Toric / N*** with a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision.

Both lenses are a flexible transparent hemispherical shell of the following dimensions:

▪ Chord Diameter:	13.6 to 15.2 mm
▪ Center Thickness (minus):	0.035 mm to 0.96 mm
▪ Base Curve:	8.3 mm to 8.9mm
▪ Spherical Powers:	-20.00 D to +20.00 D
▪ Cylinder Powers:	-0.75 to –3.00 D
▪ Add Powers:	+1.00 to +4.00
▪ Central Zone Diameter:	2.3 mm to 2.6 mm (Proclear Multifocal Toric / D) 1.7 mm to 2.0 mm (Proclear Multifocal Toric/ N)

The physical properties of the lenses are:

Refractive Index at 25° C	1.40
Light Transmittance	>90%
Water Content	59 %
Oxygen Permeability*	21.05 x 10^{-11} **(cm^2/sec) (ml O_2/ml x mm Hg) at 35 ° C. as measured by 201T Permeometer connected to a curved Rehder guard ring polarographic cell.*

510(k) Summary

7. Substantial Equivalence Table:

	SUBJECT DEVICE Proclear Toric XR Proclear Multifocal XR Proclear Multifocal Toric	PREDICATE DEVICE K050717 Proclear UltraVue Toric XR Proclear UltraVue Multifocal XR Proclear UltraVue Multifocal Toric	PREDICATE DEVICE K061948 Proclear Sphere/Asphere 1-Day Proclear Toric 1-Day Proclear Multifocal 1-Day Proclear Multifocal Toric 1-Day
Material USAN Name	Omafilcon A	Omafilcon A	Omafilcon A
FDA Category (Group)	Group II Non-Ionic High Water	Group II Non-Ionic High Water	Group II Non-Ionic High Water
Water Content	59%	59%	60%
Light Transmittance	>90%	>90%	>90%
Index of Refraction	1.40	1.40	1.40
Oxygen Permeability	21.05	21.05	20.45
Manufacturing Method	Finished Inside Polymerization System	Finished Inside Polymerization System	Cast Molded
Sterilization	Steam Validated Autoclave	Steam Validated Autoclave	Steam Validated Autoclave
Packaging	Blister Pack	Blister Pack	Blister Pack
Shelf-Life	5 Yrs.	5 Yrs.	5 Yrs.
Visibility Tint	VAT Blue #6	C.I. Reactive Blue #4	VAT Blue #6
Tinting Process	Entrapment	Reactive	Entrapment

510(k) Summary

8. Lens Design and Indications Table:

	SUBJECT DEVICE	PREDICATE DEVICE K050717	PREDICATE DEVICE K061948
	Proclear Toric XR	**Proclear UltraVue Toric**	**Proclear Toric**
Lens Design	Back Surface Toric	Back Surface Toric	Back Surface Toric
Intended Use	Correction of visual acuity in patients with myopia, hyperopia and are astigmatic	Correction of visual acuity in patients with myopia, hyperopia and are astigmatic	Correction of visual acuity in patients with myopia, hyperopia and are astigmatic
	SUBJECT DEVICE	**PREDICATE DEVICE K05717**	**PREDICATE DEVICE K061948**
	Proclear Multifocal XR	**Proclear UltraVue Multifocal**	**Proclear Multifocal**
Lens Design	Multifocal	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	Correction of visual acuity in patients with myopia or hyperopia, and are presbyopic
	SUBJECT DEVICE	**PREDICATE DEVICE K05717**	**PREDICATE DEVICE K061948**
Lens Design	Multifocal Toric	Multifocal Toric	Multifocal Toric
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	Correction of visual acuity in patients with myopia or hyperopia, and are presbyopic

9. Physiochemical Studies:

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

510(k) Summary

10. Toxicology:

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

11. 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.

12. Conclusion:

The device will be manufactured according to specified process controls and an established quality assurance program. The device will undergo the same manufacturing, packaging and sterilization procedures to devices currently marketed by CooperVision, Inc. Scottsville, NY manufacturing facility. Being similar with respect to indications for use, the risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2008

CooperVision
Bonnie Tsymbal
Director, Regulatory Affairs and Quality Assurance.
711 North Road
Scottsville NY 14546

Re: K081865
Trade/Device Name: Proclear Multifocal Toric XR, Proclear Multifocal XR, Proclear Toric XR (omafilcon A) Daily Wear Soft (hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 30, 2008
Received: September 15, 2008

Dear Ms. Tsymbal:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Indication for Use Statement

510(k) Number: K081865

Device Name: Proclear Multifocal Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses

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Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses

Indication for Use:

Proclear Multifocal Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic, possess astigmatism of 3.00 diopters or less, and are presbyopic. The 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).

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity. The 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).

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic, possess astigmatism of 5.00 diopters or less. The 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 the eye care practitioner in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

Prescription Use X (Per 21 CFR Subpart D) AND/OR Over-The-Counter ____ (Per 21 CFR Subpart C)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081865