

510k Summary of Safety and Effectiveness - K123202

MAY 30 2013

Applicant: CooperVision, Inc.
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588 USA

Applicant Contact: Karin Gastineau
Director, Global Regulatory Affairs
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Date Summary Prepared: May 1, 2013

Device Trade Names: Proclear Toric XR
Proclear Multifocal XR
Proclear Multifocal Toric
Proclear Sphere and Asphere
Proclear Toric
Proclear Multifocal

Common/Usual Name: omafilcon B Soft (Hydrophilic) Contact Lens

Classification Name: Daily Wear Soft (Hydrophilic) Contact Lens

Predicate Devices: Proclear Toric XR, Proclear Multifocal XR, Proclear Multifocal Toric, Proclear Sphere and Asphere, Proclear Toric, Proclear Multifocal (K110099, K112302)

Device Description:

The Proclear lens is composed of polymer of 2-hydroxy-ethylmethacrylate and 2-metacryloyloxyethyl phosphorylcholine cross linked with ethylene glycol dimethacrylate. The lenses are tinted blue from edge to edge for visibility purposes. The Proclear (*omafilcon B*) Soft (hydrophilic) contact lenses are a hemispherical shell. The design and toxicological properties of the devices with the modified formula to increase the water content to 62% are unchanged from predicate 510ks.

Proclear Toric and Proclear Toric XR (omafilcon B) Soft (Hydrophilic) Contact Lenses are back surface toric.

Proclear Multifocal and Proclear Multifocal XR (omafilcon B) 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

multifocal lens has two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

Proclear Multifocal Toric (*omafilcon B*) Soft (Hydrophilic) Contact Lens front surface is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic.

Proclear Sphere and Asphere: (*omafilcon B*) Soft (hydrophilic) Contact Lenses. The sphere lenses have spherical optical zone and asphere lens have an aspherical optical zone. This aspheric optical zone design (front surface) controls and limits the amount of longitudinal spherical aberration generated by the lens across the power range.

Indications for Use

Proclear Multifocal Toric (*omafilcon B*) 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 which, possess astigmatism to -5.75 diopters or less, and are presbyopic.

Proclear Multifocal XR (*omafilcon B*) 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.

Proclear Toric XR (*omafilcon B*) 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 which possess astigmatism corrections to -5.75 diopters.

Proclear Sphere and Asphere: (*omafilcon B*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-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.

Proclear Toric: (*omafilcon B*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-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.

Proclear Multifocal: (*omafilcon B*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in non-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.

Proclear (*omafilcon B*) 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 eye care practitioners in consultation with their patients.

FREQUENT PLANNED REPLACEMENT WEAR

When prescribed for frequent planned replacement wear 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.

DISPOSABLE WEAR

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

Physicochemical Studies

Results of physical, optical and chemical properties were performed and indicate no significant change to the physicochemical properties of the lenses.

Tested Characteristics	Results
Total Extractables, Water Content, Dk, Light Transmission, Refractive Index tested per ISO 18369-4:2006 <i>Ophthalmic Optics – Contact Lenses – Part 4: Physicochemical Properties of Contact Lens Materials: Section 4.2</i>	Pass

Biocompatibility

Cytotoxicity, Ocular Irritation, and Systemic Toxicity studies were performed in support of this modification. The results indicate there are no toxicity issues with the modified lens.

Clinical Studies

No clinical studies were conducted.

Conclusion Drawn from Studies

Validity of Scientific Data

All biocompatibility studies were conducted by contract laboratories under Good Manufacturing Practice regulations. Physicochemical studies were conducted by CooperVision following scientific protocols.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the CooperVision Proclear daily wear contact lenses are substantially equivalent to the predicate devices.

Substantial Equivalence Comparison		
Characteristic	Subject Devices (38% omafilcon B, 62% water)	Predicate Devices (41% omafilcon A, 59% water)
Product Names	Proclear Toric Proclear Toric XR Proclear Multifocal Proclear Multifocal XR Proclear Multifocal Toric Proclear Sphere Proclear Asphere	Proclear Toric Proclear Toric XR Proclear Multifocal Proclear Multifocal XR Proclear Multifocal Toric Proclear Sphere Proclear Asphere
Indications for Use	Same	Same
Material USAN Name	omafilcon B	omafilcon A
FDA Category (Group)	Non-Ionic High Water	Non-Ionic High Water
Manufacturing Method	Finished Inside Polymerization System	Finished Inside Polymerization System
Curing	Thermal Cure	Thermal Cure
Sterilization	Moist Heat (steam)	Moist Heat (steam)
Packaging	Blister Pack	Blister Pack
Package Saline Buffers and Surfactant	Phosphate buffers PEG200 and Tween 80	Phosphate buffers PEG200 and Tween 80
Refractive Index	1.390 ± 0.005	1.395 ± 0.005
Oxygen Permeability x 10⁻¹¹	27.00 ± 20%	21.05 ± 20%
Light Transmission	>90%	>90%
Base Curve	8.0 to 9.3 mm	8.0 to 9.3 mm
Diameter	13.6 to 15.2 mm	13.6 to 15.2 mm
Power	-20.00 to +20.00	-20.00 to +20.00
Water Content	62% ± 2%	59% ± 2%



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

May 30, 2013

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

Ms. Karin Gastineau
Director, Global Regulatory Affairs
CooperVision, Inc.
6150 Stoneridge Mall Road
Pleasanton, CA 94588

Re: K123202

Trade/Device Name: Proclear (omafilcon B) Soft (Hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 30, 2013
Received: May 2, 2013

Dear Ms. Gastineau:

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

Indications for Use Statement

510(k) Number (if known): K123202

Device Name: Proclear (omafilcon B) Soft (Hydrophilic) Contact Lens

Indications for Use:

Proclear Multifocal Toric (omafilcon B) 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 which, possess astigmatism to -5.75 diopters or less, and are presbyopic.

Proclear Multifocal XR (omafilcon B) 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.

Proclear Toric XR (omafilcon B) 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 which possess astigmatism corrections to -5.75 diopters.

Proclear Sphere and Asphere: (omafilcon B) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-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.

~~**Proclear Toric:** (omafilcon B) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-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.~~

Proclear Multifocal: (omafilcon B) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in non-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.

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DISPOSABLE WEAR

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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)

Marc Robboy

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose
and Throat Devices
510(k) Number **K123202**