K111966

SEP 15 2011

CooperVision

510(k) Summary

1. Applicant Name and Address

CooperVision, Inc.
6150 Stoneridge Mall Drive
Suite 370
Pleasanton CA 94588

2. Contact

Lisa Hahn
Global Regulatory Affairs
585-385-6810 ext 4221
lhahn@coopervision.com

3. Date Prepared

Original July 1, 2011

3. Device Identification

Trade Name:	Proclear 1 day Proclear
Common Name:	Disposable Soft Contact Lenses, or Scheduled Replacement Soft Contact Lenses
Classification Name:	Disposable, Daily Wear Soft Contact lens Daily Wear, Soft (hydrophilic) Contact Lenses
Device Classification:	Class II (21 CFR 886.5925)
FDA Material Class:	FDA Group II Non-Ionic High Water Content
Product Code:	MVN, LPL

4. Device Description

The Proclear lens is composed of polymer of 2-hydroxy-ethylmethacylate and 2-metacryloloyoxyethyl phosphorylcholine cross linked with ethylmethacrylate. The lenses are tinted blue from edge to edge for visibility purposes. The Proclear *(omafilcon A)* Soft (hydrophilic) contact lenses are a hemispherical shell. The physical properties and available dimensions are unchanged from predicate 510ks.
The modifications to the stability – shelf life protocol include alternate test method for package integrity and adjusted storage temperatures for the packaged products that will be tested using alternate package integrity test method.

5. Intended Use

Proclear 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)

Proclear Daily Wear (*Omafilcon A*) Soft Contact Lenses (K952152)
Proclear Compatibles Daily Wear (*Omafilcon A*) Soft Contact Lenses (K970095)
Proclear and Proclear Compatibles (*Omafilcon A*) Soft Contact Lenses (K974408)
Proclear Compatibles Multifocal (*Omafilcon A*) Soft Contact Lenses (K032873)
Proclear Multifocal (*Omafilcon A*), Proclear Toric (*Omafilcon A*) and Proclear Multifocal Toric (*Omafilcon A*) Soft Contact Lenses (K050717)
Proclear XC and Proclear 1 Day (*Omafilcon A*) Soft Contact Lenses (K061948)

7. Characteristics of Substantial Equivalence

The soft contact lenses have the following similarities to the predicate lenses which previously received 510(k) concurrence:

- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

In summary, the omafilcon A soft contact lenses described in this submission are, substantially equivalent to the predicate devices.

8. Physiochemical Studies

Results from physical, optical and chemical properties were not required as support for this modification to shelf life protocol. Change will not affect physicochemical properties of the lenses.

9. Toxicology Studies

Results from in-vivo and in-vitro studies were not required as support for this modification to shelf life protocol. Change will not affect lenses ability to remain non-toxic and biocompatible with the ocular environment.

10. Conclusions of Non-Clinical Tests Performed:

- **Physiochemical:**

  The physical, optical and chemical properties of this lens remain unchanged from the unmodified device, and are within established specifications for the lenses.

- **Toxicology:**

  Results from in-vivo and in-vitro studies originally conducted remain valid 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 not changing and therefore are equivalent to omafilcon A soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

12. Conclusions

Based on no change to material, no change to manufacturing methods, no change to lens parameters and no change to indicated use, the omafilcon A soft contact lens described in this document is substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

CooperVision, Inc.
c/o Ms. Lisa Hahn
Global Regulatory Affairs
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588

SEP 15 2011

Re: K111966
Trade/Device Name: Proclear (Omafilcon A) Soft (Hydrophilic) Contact Lenses:
Proclear Daily Wear (Omafilcon A) Soft Contact Lenses
Proclear Compatibles Daily Wear (Omafilcon A) Soft Contact Lenses
Proclear and Proclear Compatibles (Omafilcon A) Soft Contact Lenses
Proclear Compatibles Multifocal (Omafilcon A) Soft Contact Lenses
Proclear Multifocal (Omafilcon A), Proclear Toric (Omafilcon A), and
Proclear Multifocal Toric (Omafilcon A) Soft Contact Lenses
Proclear XC and Proclear 1 Day (Omafilcon A) Soft Contact Lenses
Proclear Multifocal (Omafilcon A), Proclear Toric (Omafilcon A) and
Proclear Multifocal Toric (Omafilcon A) Soft Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL and MVN
Dated: August 31, 2011
Received: September 1, 2011

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. 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,

Kesia Alexander

for

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): K111966

Device Name: Proclear (omafilcon A) Soft (hydrophilic) Contact Lenses

Indications for Use:

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.

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise Hanyk

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111966