NOV - 7 2003

K032873

510(k) Summary: Addresses requirements by the Safe Medical Devices Act of 1990 to summarize the safety and effectiveness information upon which the substantial equivalence for alternate lens design configuration determination is based.

1. Submitter Information

CooperVision, Inc.
1215 Boissevain Ave
Norfolk VA 23507

Contact person: Lisa Hahn
Director of Quality and Regulatory Affairs
Phone: (757) 664-2421
Fax: (757) 623-5019

2. Identification of Device

Classification name: Daily Wear Soft Hydrophilic Contact Lenses

Proprietary name: Proclear Compatibles Multifocal (omafilcon A) Soft (Hydrophilic) Contact Lenses

Device classification: Class II (21 CFR 886.5925)

3. Predicate Devices

Proclear Compatibles (omafilcon A)	Premarket Notification # K970095
Frequency 55 Multifocal (methafilcon A)	Premarket Notification # K002625

4. Indications for Use

Proclear Compatibles 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 aphakic and/or 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.

These 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. 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.

5. Device Description

The Proclear Compatibles Multifocal (omafilcon A soft (hydrophilic) contact lens is available as hemispherical flexible shell which covers the cornea and may cover a part of the adjacent sclera. Lens material, omafilcon A is a random copolymer of hydroxyethylmethacrylate and 2-methacryloyloxyethyl phosphorycholine cross-linked with ethylene glycol dimethacrylate. The lenses are tinted from edge to edge for visibility purposes with the color additive, Reactive Blue No. 4.

Proclear Compatibles Multifocal contact lens is hemispherical shell of the following dimensions:

- Diameter: 14.2mm to 15.0mm
- Base curve: 8.0mm to 9.5mm
- Center Thickness: 0.15mm to 0.96mm varies with power
- Powers: -20.00 to +20.00 D
- Add powers: +0.50 to +4.00 D

The physical properties of the lens are:

- Refractive Index: 1.38
- Light Transmittance >95%
- Surface Character: Hydrophilic
- Water Content 62%
- Oxygen Permeability 27 x 10-11 (cm2/sec)(ml O2/ml x mmHg) at 35° C (modified ISO method for determination of oxygen permeability)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2003

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

Re: K032873
Trade/Device Name: Proclear Compatibles Multifocal (omafilcon A) Soft Contact Lenses For Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Daily wear soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL
Dated: September 12, 2003
Received: September 15, 2003

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032873

Device name: Proclear Compatibles Multifocal

Indications for use:

Proclear Compatibles 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 aphakic and/or 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.

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTOHER 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 K032873

Prescription Use X OR Over-The-Counter _____
(per 21 CFR 801.109)