DEC 6 2005

K052560

CooperVision®

510(k) SUMMARY

1. Applicant Name and Address

CooperVision, Inc.
5870 Stoneridge Dr.
Suite 1
Pleasanton, CA 94588
USA
(800) 972-6724

2. Contact

Jack P. Douglas, Ph.D.
Dept. of Regulatory Affairs
(925) 251-6666

3. Manufacturer Information

CooperVision, Inc.
Hamble Ln.
Hamble
SO31 4NH
United Kingdom
Contact: Martin Newman
Telephone: +44 (0) 7795 414 801

4. Device Identification

Common Name:	Soft Contact Lens
Trade Name:	BIOFINITY (*comfilcon A*) Soft Contact Lens
Class. Name:	Soft (hydrophilic) Contact Lens – Daily Wear
Classification:	Class II [21 CFR 886.5925]
Product Code:	LPL

5. Device Description

The BIOFINITY (*comfilcon A*) soft contact lens is a Group I, daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high oxygen permeability (Dk). The lens material, *comfilcon A*, is composed of silicone macromers cross linked with other monomers, incorporating phthalocyanine blue as an integrated, handling tint. The lenses are made by cast molding. The lens will be manufactured in spherical, aspherical, toric and multifocal configurations with the following features and properties:

• Chord Diameter	• 13.5 mm to 15.0 mm
• Center Thickness	• 0.05 mm to 0.50 mm
• Base Curve	• 8.0 mm to 9.5 mm
• Power Range	• -20.00D to +20.00D in 0.25 steps
• Cylinder Power (Toric)	• -0.25 to -10.00 D
• Add Power (Multifocal)	• +0.50 to +3.00D
• Refractive Index (hydrated)	• 1.40
• Water Content	• 48% by weight in normal saline
• Oxygen permeability	• 128×10^{-11} [$(cm^2/sec)(ml\ O_2)/ml*mmHg$], 34°C, Coulometric method

The lens is supplied sterile in blister packs containing a buffered saline solution. Blister labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

6. Intended Use

SPHERICAL AND ASPHERICAL:

BIOFINITY (*comfilcon A*) SPHERE and ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

TORIC:

BIOFINITY (*comfilcon A*) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MULTIFOCAL:

BIOFINITY (*comfilcon A*) multifocal lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The BIOFINITY (comfilcon A), BIOFINITY Toric (comfilcon A) and BIOFINITY Multifocal (comfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for frequent replacement/planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting systems.

7. Predicate Device(s)

- CIBA Vision SEE3™ (*lotrafilcon A*) Soft Contact Lenses [K970746]
- CIBA Vision O_2OPTIX™ (*lotrafilcon B*) Soft Contact Lenses [K033919]

CooperVision®

8. Characteristics of Substantial Equivalence

The BIOFINITY (*comfilcon A*) Soft Contact Lens is substantially equivalent to the CIBA Vision SEE3™ (*lotrafilcon A*) and CIBA Vision O_2OPTIX™ (*lotrafilcon B*) Soft Contact Lenses. All of these lenses are categorized as Group I (low water, nonionic) silicone hydrogel lenses. All of these lenses are Class II and have indications for daily wear per premarket notification. The following Table summarizes the primary features for this comparison, illustrating the similarities and differences.

	CooperVision BIOFINITY [Current Submission]	**CIBA Vision SEE3™ [K970746]**	**CIBA Vision O_2 Optix™ [K033919]**
Material	*comfilcon A* silicone hydrogel	*lotrafilcon A* silicone hydrogel	*lotrafilcon B* silicone hydrogel
Category (Group)	Group I (low water, nonionic)	Group I (low water, nonionic)	Group I (low water, nonionic)
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded
Indication	Daily Wear	Daily Wear	Daily Wear
Replacement	Monthly	Monthly	Two weeks
Water Content (%)	48	24	33
Oxygen Permeability - Dk @ 34°C [(cm^2/sec) x (ml O_2)/(ml x mm Hg)]*	128×10^{-11}	140×10^{-11}	110×10^{-11}
Refractive Index	1.40	1.43	1.42
Light Transmittance (%)	> 97	> 99	> 96
Modulus (MPa)	0.8 ± 0.1	1.4 ± 0.1	1.0 ± 0.1
Tensile Strength (Mpa)	0.50 ± 0.07	0.80 ± 0.08	0.73 ± 0.16
Elongation to Break (%)	130 ± 2	128 ± 22	186 ± 39
Surface Treatment	No	Yes	Yes
Color Additive	Phthalocyanine Blue	None	Phthalocyanine Blue
Tint Process	IMT	N/A	IMT
Chord Diameter Range(mm)	13.5 to 15.0	13.0 to 15.0	13.0 to 15.0
Base Curve Range (mm)	8.0 to 9.5	8.0 to 9.2	8.0 to 9.2
Center Thickness (mm)	0.08 @ -3.00D	0.08 @ -3.00D	0.08 @ -3.00D
Power Range	-20.00D to +20.00D	-20.00D to +20.00D	-20.00D to +20.00D
Chord Diameter (Nominal)	14.0	13.8	14.2
Base Curve	8.6	8.4, 8.6	8.6
Powers	-20.00D to +20.00D in 0.25 steps	+0.25 to +6.00, 0.25D steps - 0.25 to -8.00, 0.25D steps - 8.50 to -10.00, 0.50D steps	-1.00 to -6.00, 0.25D steps

* coulometric method

9. Physicochemical Studies

The physical, optical and chemical properties of the lenses as assessed by various test methods show substantial equivalency with the predicate devices as illustrated in the preceding table. Additional studies were conducted to verify that leachable substances were either low or below measurable levels to assuage any concerns for its intended use.

10. Toxicology Studies

Animal GLP studies were conducted and determined that BIOFINITY lenses were biocompatible for the intended use as assessed using ISO 10993 standards for cytotoxicity, maximization sensitization, ocular irritation, and systemic toxicity. All results passed with no evidence of adverse clinical effects caused by the BIOFINITY lens.

11. Human Clinical Studies

Clinical studies were conducted to demonstrate substantial equivalence of the BIOFINITY lens as compared with the CIBA Vision Focus Night & Day based on performance and safety. In a study of daily wear, assessment of visual acuity performance showed no significant difference between the two products. Safety as assessed by patient complaints or/and slit lamp observations showed no significant difference of clinical adverse events between the two products. There were no serious or significant adverse events attributable to the device during the study.

12. Conclusions

Based on evaluations of material, manufacturing methods, lens parameters and indicated use, the BIOFINITY lens is substantially equivalent with the predicate, marketed lenses. Based on evaluation of chemical properties, biocompatibility and clinical studies, the BIOFINITY lens has been 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

DEC 6 2005

Cooper Vision, Inc.
c/o Jack P. Douglas, Ph.D.
5870 Stoneridge Dr.
Suite 1
Pleasanton, CA 94588

Re: K052560
Trade/Device Name: Biofinity (comfilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: September 15, 2005
Received: September 16, 2005

Dear Dr. Douglas:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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]: K052560

Device Name: BIOFINITY (*comfilcon A)* Soft Contact Lens

Indications for Use:

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Additional Claims:

(PLEASE DO NOT 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 K052560

Prescription Use ✓
(Per 21 CFR 801.109)