K040900 JUN 15 2004

Optical Connection Inc.

510(k) Summary

Submitter Information:

Optical Connection, Inc.
a subsidiary of St. Shine Optical Co., Ltd.
3315 Almaden Expressway,
Suite 25
San Jose, CA, 95125

Contact Person: Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant

Telephone: (408) 221-3860
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Date Prepared: March 23, 2004

Device Name:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:	S 42 UV Single Vision (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
	T 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
	M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Devices:
The molded Specialty 42 UV, Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses and Saview 55 Multifocal (methafilcon A) Soft (Hydrophilic Contact Lens were selected as the predicate devices.

Specialty 42 UV, Specialty 42 UV Toric (hefilcon A) and Saview 55 Multifocal (methafilcon A) devices are manufactured in the same facility, under the same quality system, using the same molding, tinting, packaging and sterilization processes.

Description of Devices:

S 42 UV Single Vision, T 42 UV Toric, and M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells that cover the cornea and a portion of the adjacent sclera. The 42 UV Contact Lens is available in a single vision lens design, the 42 UV Toric Contact Lens is available in a back surface design, and the 42 UV Multifocal lens is available in an aspheric lens design. The lens material (hefilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and n-vinyl-2-pyrrolidone (NVP) cross-linked with ethyleneglycol dimethacrylate (EGDMA), using AIBN as the initiator. The lens contains 42% water by weight. 42 UV, 42 UV Toric, and 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are tinted using Pigment Blue 15, ([Phthalocyaninato(2-)] copper) which is approved for coloring contact lenses under 21 CFR § 74.3045 and a UV absorbing compound, 2-(benzoyl-3-hydroxyphenoxy)ethyl acrylate, has been incorporated into the lens polymer.

Comparison to Predicate Devices

Lens type ***Predicate device 510(k)***	***S 42 UV Single Vision, T 42 UV Toric and M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear (molded)***	***S 42 UV Single Vision, T 42 UV Toric and M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear (lathe-cut)***	***Specialty 42 and Specialty 42 Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear*** ***K000376***	***Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear*** ***K011089***	***Saview 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear*** ***K030548***
Material	hefilcon A	hefilcon A	hefilcon A	hefilcon A	methafilcon A
Material classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1	Hydrophilic Lens Group 4
Indication for use	myopia, hyperopia, astigmatism, and presbyopia	myopia, hyperopia, astigmatism, and presbyopia	myopia, hyperopia and astigmatism	myopia, hyperopia and astigmatism	myopia, hyperopia and presbyopia
Water content	42%	42%	42%	42%	55%
Visible light transmittance	98%	98%	98%	98%	97.6%
UV transmittance	< 10%	< 10%	N/A	< 10%	N/A
Dk (35° C)	13.375×10^{-11}	13.375×10^{-11}	13.250×10^{-11}	13.375×10^{-11}	19.5×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters	+12.00 to –20.00 Diopters; continuous add power to +3.25
Color	blue visibility	blue visibility	clear or blue visibility	blue visibility	blue visibility
Refractive index	1.416	1.416	1.417	1.416	1.3974 (wet)
Specific gravity	1.039	1.039	1.031	1.039	N/A
Method of manufacture	Molded	Lathe-cut	Moulded	Molded	Molded

Indications for Use:

The **S 42 UV Single Vision (hefilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The T 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

The **M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using chemical (not heat) or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical (not heat), or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of S 42 UV Single Vision, T 42 UV Toric, and M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. 42 UV lenses were extracted and evaluated for presence of the UV blocking compound. Results showed no evidence of unsafe amounts of this compound in the extracts. Physicochemical testing of 42 UV lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that S 42 UV Single Vision, T 42 UV Toric, and M 42 UV Multifocal (hefilcon A) contact lenses have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

Optical Connection, Inc.
c/o Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant
3315 Almaden Expressway, Suite 25
San Jose, CA 95118

Re: K040900
Trade/Device Name:
S 42 UV Single Vision (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear (Molded)
T 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear (Molded)
M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear (Molded)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 23, 2004
Received: April 6, 2004

Dear Dr. Edwards:

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.

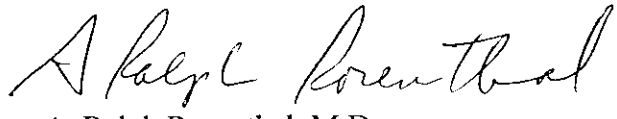
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number: K040900

Device Names:

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M 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The lenses may be disinfected using chemical (not heat) or hydrogen peroxide, disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K040900