MAR 1 0 2006

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051477

Applicant information:

Date Prepared:	January 30, 2006
Name:	**MiGwang Contact Lens Co. Ltd.**
Address	116-2, Hyupsuk-ri Namchunmyun, Kyoungsan, Kyoungbuk, Korea
Contact Person:	Mr. Ssang Gi, Kim
Phone number:	82-53-811-2262
USA Consultant:	Med-Vice Consulting, Inc. Martin Dalsing
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear

Trade Name: **MiGwang Comfort 38 (polymacon) Spherical and Toric Soft Contact Lens for Daily Wear (clear & tinted)**

Purpose of 510(k) Submission:

The MiGwang Contact Lens Company proposes to manufacture, market and sell into United States interstate commerce, a soft contact lens of the (polymacon) soft contact lens material and made available in a spherical and toric product configuration. Data supporting substantial equivalency to predicate devices, and safety and efficacy of the (polymacon) polymer is contained in this submission.

Equivalent Devices:

MiGwang Comfort 38 (polymacon) Spherical and Toric Soft Contact Lens for Daily Wear is substantially equivalent to the following predicate devices:

Predicate devices:

- "Advantage 38" (polymacon) manufactured by Preferred Optics.
- "ContaFlex 38" (polymacon) manufactured by Contamac Ltd.

Device Description:

The MiGwang Comfort 38 (polymacon) Soft Contact Lenses are hemispherical shells with molded spherical base curves and lathe-cut front surfaces. The MiGwang Comfort 38 soft contact lens is fabricated from a nonionic polymer.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2- Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. The lenses are available clear or tinted. Lenses are tinted with one or a combination of one or more of the following 'listed' color additives: C.I. Reactive black 5, C.I. Vat orange 5, Iron oxides, C.I. Pigment green 7, C.I. Vat brown 1, C.I. Vat yellow 3, C.I. Vat blue 6, C.I. vat orange 1, C.I. Vat green 1, C.I. Pigment blue 36, C.I. Pigment violet 23, D&C Green No.6, phthalocyanato (2) copper, D&C Yellow No. 10, D&C Red No. 17 and Titanium dioxide. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 90%
Light Transmission (tinted)	greater than 90%
Water Content	38 % ± 2%
Oxygen Permeability	9.77×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ $35^{\circ}C$), (revised Fatt method).

Intended Use:

The **MiGwang Comfort 38 (polymacon) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **MiGwang Comfort 38 (polymacon) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eyecare practitioners may prescribe the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Substantial Equivalence:

The **MiGwang Comfort 38** Soft Contact Lens will be manufactured according to specified process controls and a cGMP quality assurance program currently in place. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **MiGwang Comfort 38** contact lens material is equivalent to the predicate devices identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies of the **MiGwang Comfort 38** Spherical and toric Soft Contact Lens, as well as the substantial equivalent predicate devices.

Substantial Equivalence Matrix

Substantial Equivalency	MiGwang Comfort 38	Advantage 38	Contaflex 38
Manufacture	MiGwang Contact Lens Company	Preferred Optics	Contamac Ltd.
INDICATION	Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters, and/or are presbyopic NOTE: refractive astigmatism and presbyopia N/A for spherical lenses.	Soft Contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.50 diopters NOTE: refractive astigmatism N/A for spherical lenses.	Soft Contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism in aphakic and not aphakic persons with non-diseased eyes NOTE: refractive astigmatism N/A for spherical lenses.
INTENDED USE	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Manufacturing Method	Lathe-cut (Semi-Molded)	Lath-Cut	Lath-Cut
USAN name Material name	polymacon	polymacon	polymacon
Water Content (%)	37%	38%	37%
Toxicity (safety)	Non-Toxic	Non-Toxic	Non-Toxic

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

MiGwang Contact Lens Co., Ltd.
c/o Mr. Martin Dalsing
Medvice Consulting Inc.
2214 Sanford Drive, B7
Grand Junction, CO 81505

Re: K051477
Trade/Device Name: MiGwang Comfort 38 (polymacon) Spherical and Toric Soft Contact Lens for Daily Wear (clear and tinted)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 30, 2006
Received: February 1, 2006

Dear Mr. Dalsing:

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,

Malvina B. Eydelman, M.D.
Acting Division 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

Device Name: **MiGwang Comfort 38 (polymacon) Spherical and Toric Soft Contact Lens for Daily Wear (clear & tinted)**

INDICATIONS FOR USE:

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The **MiGwang Comfort 38 (polymacon) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Prescription Use X
(Per 21 CFR 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)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051477