DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 7, 2014

Neo Vision Co., Ltd.
% Albert Rego Ph.D.
Regulatory Consultant
Albert Rego, Ph.D., Inc.
27001 La Paz Road, Suite 312
Mission Viejo, CA 92691

Re: K142275
Trade/Device Name: Neo Cosmo (polymacon) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: July 31, 2014
Received: August 15, 2014

Dear Dr. Rego:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142275

Device Name
Neo Cosmo (polymacon) Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*

The Neo Cosmo (Polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens frequent replacement wear with cleaning, disinfecting and schedule replacement. The lens may be disinfected using a chemical (not heat) lens care system only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
(As required by 21 CFR 807)

SUBMITTED BY	Neo Vision Co., Ltd. 17th Floor, U-Tower, 1029 Yeongdeok-Dong, Giheung-gu, Yongin-si Gyeonggi-do Korea
CONTACT	Kyung Hwa Kim 82-31-889-2040 export@neolens.co.kr
SUBMISSION DATE	April 7, 2014
TRADE NAME	Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens - Neo Cosmo
COMMON NAME	Lenses, Soft Contact, Daily Wear
CLASSIFICATION NAME	Class ll (21 CFR 886.5925)
PRODUCT CODE	LPL
PREDICATE DEVICE	K051477 Migwang Comfort 38 Decision Date: 03/10/2006

DEVICE DESCRIPTION

Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens for Daily Wear is available as a single vision lens. The lens material, polymacon is hydrophilic polymer of 2-hydroximethyl methacrylate (HEMA) cross-linked with ethyleneglycol dimethacrylate(62%) and water(38%).

Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens for Daily Wear is colored with one or a combination of one or more of the following color additives: Titanium dioxide (white), C.I Pigment blue 36, Iron oxides, C.I. Pigment green 7, C.I. Pigment violet 23, D&C Yellow No.10.

Neo Vision Neo Cosmo is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera with the following dimensions:

- Diameter: 13.8mm to 14.5mm
- Base Curve: 8.0mm to 9.0mm
- Center Thickness: 0.05mm to 0.135 (varies with power)
- Powers: 0.00D to -10.00D

The physical properties of the lens are:

- l Refractive Index: 1.43
- l Light Transmittance: >95%
- l Water Contents: 38%
- l Oxygen Permeability: 9.5 X 10-11(cm2/s) [ml O2 / (ml X mmHg) at 35°C

Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact lens consists of:

No.	Part Name	Raw Material	Composition (%)	Remark	Function
1	Base	2-hydroxyethylmethacrylate	99.3	CAS No. 868-77-9	Main Element
		Ethylene glycol dimethacrylate	0.7	CAS No. 97-90-5	Cross-linker
2	Color Additive	Titanium dioxide (white)	≤ 0.04	CFR No. 73.3126	Color
		Iron oxides		CFR No. 73.3125	Color
		C.I. Pigment violet -23		CFR No. 73.3107	Color
		D & C Yellow No. 10		CFR No. 73.3110a	Color
		C.I. Pigment green -7		CFR No. 73.3124	Color

Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact lens is packaged in either in a vial package or a blister package.

The vial package is a 5mL Borosilicate glass vial filled with NaCl 0.85˜0.95 w/v% solution. The cap is aluminum with a locking rubber (Chlorobutyl rubber for medical use).

The blister package consists of 3mL Polypropylene filled with NaCl 0.85˜0.95 w/v% solution with an aluminum sealing film sheet.

INDICATIONS FOR USE

The Neo Cosmo (Polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens frequent replacement wear with cleaning, disinfecting and schedule replacement. The lens may be disinfected using a chemical (not heat) lens care system only.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the predicate devices in its intended use and technological characteristics, manufacturing process specified in following table;

Substantial Equivalency	Soft (hydrophilic) contact lens	
Manufacture	MiGwang Contact Lens Co., Ltd.	Neo Vision
Article name	Migwang Comfort 38	Neo Cosmo
Material USAN name	Polymacon	Polymacon
Type	Spherical, Toric	Spherical, Toric
FDA Classification	Lenses, Soft Contact, Daily Wear (Class II)	Lenses, Soft Contact, Daily Wear (Class II)
Water Content	38±2%	38±2%
Light Transmittance	>90%	>90%
Index of Refraction	1.43	1.428
Oxygen permeability	$9.77 * 10^{-11}$ (cm^2/sec)(ml O_2/ml * mm Hg @ 35℃)	$9.77 * 10^{-11}$ (cm^2/sec)(ml O_2/ml * mm Hg @ 35℃)
Manufacturing Method	Lathe-cut (semi molded)	Lathe-cut (semi molded)
Sterilization	Steam Validated Autoclave	Steam Validated Autoclave
Packaging	Blister Pack & vial	Blister Pack & vial
Visibility tint	Titanium Dioxide; 21CFR 73.3126	Titanium Dioxide(White); 21CFR 73.3126
Visibility tint	Iron Oxides; 21CFR 73.3125	Iron Oxides(Red); 21CFR 73.3125
Visibility tint	C.I Pigment Green 7; 21CFR 73.3124	C.I Pigment Green 7; 21CFR 73.3124
Visibility tint	(Phthalocyaninato(2-)) Copper; 21CFR 74.3045	(Phthalocyaninato(2-)) Copper; 21CFR 74.3045
Visibility tint	C.I. Reactive Black 5 21CFR 73.3121	Reactive Black 5 21CFR 73.3121
Tint Process	Entrapment	Entrapment
Indication	Soft Contact Lenses for daily wear are indicated for the correction of visual in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopter, and/or are presbyopia. NOTE: Refractive astigmatism and presbyopia N/A for spherical lenses.	The Neo Vision Neo Cosmo (Polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual

		acuity. The lens is available clear or colored and may be sued to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens frequent replacement wear with cleaning, disinfecting and schedule replacement. not exceeding 5.00 diopter, and/or are presbyopia.
Powers	+25.00 ~ -25.00 Diopter	+25.00 ~ -25.00 Diopter
Total diameter	12.8 ~ 14.8	13.5 ~ 14.5
Geometrical center thickness	0.03 ~ 0.30	0.03 ~ 0.50
Curvature	8.0 ~ 9.5	8.3 ~ 9.0
Optic zone	6.0 ~ 12.5	6.0 ~ 12.5
Radial edge thickness	0.03 ~ 0.12	0.03 ~ 0.05
Color	brown, gray, aqua, blue, violet, green	brown, gray, aqua, blue
Toxicity(Safety)	Non-Toxic	Non-Toxic
Tensile Strength (MPa)	0.427	0.425
% Elongation to Break	128%	127%
Module of Elasticity (MPa)	0.338	0.350
Breaking Force (N)	0.449	0.439

SUMMARY NON-CLINICAL TESTING

The Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens has been subjected to property evaluation, moist heat (steam) sterilization evaluation and biocompatibility evaluation, and has successfully passed all testing.

PERFORMANCE TESTING

TEST TITLE	FINAL REPORT NUMBER	TEST RESULT
Tensile Testing	TP-001/TR-001	Pass
Solution Compatibility (Cleaning Cycle Testing)	Protocol per FDA Guidance – Attached/ Report 13-0400	Pass
Physical Properties of the Neo Cosmo	MTK-6310	Pass
Physical Properties of the Neo Vision Neo Cosmo	MSK-1241	Pass
Physical Properties of the NEO Toric	MSK-1242	Pass

Physical Properties of the NEXT	MSK-1243	Pass
Physical Properties of the NEW GREEN	MSK-1244	Pass
Physical Properties of the NEO CLEAN	MSK-1245	Pass

BIOCOMPATIBILITY TESTING

TEST TITLE	FINAL REPORT NUMBER	TEST RESULT
Ocular Irritation Test	MTK-6310	Pass
Skin Sensitization Test	MTK-6310	Pass
Cytotoxicity Test (Proliferation Inhabition Test)	MTK-6310	Pass
Cytotoxicity Test (Agar Diffusion Test)	MTK-6310	Pass
Ocular Irritation Study of Neo Cosmo Soft Contact Lens in NZW Rabbits	TBH-0375 (KG-2013-121)	Pass
Skin Sensitization Study of Neo Cosmo soft contact lens using Guinea-Pig Maximization Test (GPMT)	TBH-0376 (KG-2013-122)	Pass

SUMMARY CLINICAL TESTING

The Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens was not evaluated with clinical testing.

CONCLUSION

Based on analyzing the device characteristics, bench performance and sterilization testing, and biocompatibility testing, it is the conclusion of Neo Vision Co., Ltd., that the Neo Vision Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact lens is safe and effective for its intended use.