



December 12, 2014

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Qualimed SRL
c/o Mr. Bret Andre
EyeReg Consulting, Inc.
474 NE 61st PL
Hillsboro, OR 97124

Re: K142384

Trade/Device Name: DESIO (polymacon) Daily Wear Soft (hydrophilic)
Contact Lenses (Clear and Tinted)

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL; MVN

Dated: November 6, 2014

Received: November 10, 2014

Dear Mr. Andre:

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" (21CFR 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

Indications for Use

510(k) Number (if known)
K142384

Device Name
DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted)

Indications for Use (Describe)

The DESIO (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 DESIO (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 4.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

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.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K142384

Applicant information:

Date Prepared: November 6th , 2014

Name: **QUALIMED SRL**
PIAZZA DELLA RADIO 37
00146 ROMA
ITALY

Contact Person: Ms. Tereza Uhrova
Legal Representative

Phone number: +39 3336002851

Consultant: Bret J Andre
EyeReg Consulting, Inc.
474 NE 61st PL
Hillsboro, OR 97124
United States

Phone number: (503) 372-5226

Device Information:

Device Classification: Class II

Product Code: LPL; MVN

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Trade Name: **DESIO (polymacon) Daily Wear Soft (hydrophilic)
Contact Lenses (Clear and Tinted)**

Equivalent Devices:

DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted) are substantially equivalent to the following predicate devices:

Predicate device(s):

- **“ISENS”**
By Vision Science Co., Ltd.
510(k) number; K132714

Device Description:

The DESIO soft contact lenses are hemispherical shells with molded spherical base curves and molded front surfaces. All lenses containing dioptric powers outside +/- 10.00 D and toric lenses are lathe-cut to specified Rx. The DESIO soft contact lenses are fabricated from polymacon, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

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 saline solution. The (polymacon) name has been adopted by the United States Adopted Names Council (USAN).

DESIO lenses are available clear or tinted to enhance or alter the apparent color of the eye. Lenses are tinted with one or a combination of one or more of the following ‘listed’ color additives:

Name of Colorant	Listing
D&C Yellow 10	21 CFR § 74.3710
Titanium Dioxide	21 CFR § 73.3126
Iron Oxide (Red)	21 CFR § 73.3125
[Phthalocyaninato(2-)] Copper	21 CFR § 74.3045
Phthalocyanine Green	21 CFR § 73.3124
Carbazole Violet	21 CFR § 73.3107
Reactive Blue 19	21 CFR § 73.3127
C.I. Reactive black 5	21 CFR § 73.3127

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. When producing the tinted lenses, the manufacturing process alters and/or

changes the specifications to the clear version of a contact lens by affixing a listed reactive color additive in the center of the contact lens (between layers of contact lens material) in a location that corresponds to the iris. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens. The tinting pattern has a standard Clear Pupil diameter of 6.0 mm.

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 physical properties of the lens are:

Refractive Index	1.43
Light Transmission (clear)	greater than 96%
Light Transmission (tinted)	greater than 96% (at region corresponding to pupil); Opaque or 0-10% (at region corresponding to iris)
Surface Character	hydrophilic
Water Content	38±2%
Specific Gravity	1.17 (hydrated)
Oxygen Permeability	12.48 x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. The lenses will be manufactured in spherical and toric configurations with the following features and properties:

Chord Diameter:	12.80 mm to 15.00 mm
Center Thickness:	0.050 mm to 0.210 mm
Base Curve:	8.0 mm to 9.8 mm
Power Range	
Cast-molded:	-10.00D to +10.00D in 0.25D steps
Lathe-cut:	-20.00D to -10.00D & +20.00D to +10.00D in 0.25D steps
Cylinder Power (Toric):	-0.25D to -4.00D in 0.25D steps (lathe-cut)
Cylinder Axis (Toric):	10° to 180° in 10° steps

DESIO lenses are supplied in blister packages with a base made from polypropylene and a laminated foil seal on top. The lenses are supplied sterile in Polyhexamethylene Biguanide (PHMB) containing saline solution. Blister package labeling is printed with the 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.

Intended Use:

The **DESIO (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 **DESIO (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 4.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

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.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

Testing:

Non-clinical Testing A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **DESIO** (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses packaged in blister packages. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols. Test results of the non-clinical testing on the **DESIO** (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses demonstrate that:

- Lenses supplied in blister packages are sterile for the indicated shelf-life,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data The clinical performance of the (polymacon) lens material has been previously established, and therefore was not required for this 510(k).

Conclusions Drawn from StudiesValidity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, microbiology, chemistry, shelf-life stability studies and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **DESIO**, (polymacon) Spherical and Toric Soft Contact Lenses for Daily Wear is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of daily wear soft contact lenses. The benefits to the patient are the same as those for other daily wear soft contact lenses.

Substantial Equivalence:

The **DESIO** 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 **DESIO** 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 **DESIO** Spherical and Toric Soft (hydrophilic) Contact Lens, as well as the substantial equivalent predicate devices.

Substantial Equivalence Matrix

	QUALIMED SRL DESIO (polymacon) New Device	Vision Science Co. Ltd., ISENS (polymacon) Predicate Device
Intended Use	Indicated for daily wear 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 4.00 diopters. NOTE: refractive astigmatism N/A for spherical lenses.	Indicated for daily wear 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 4.00 diopters. NOTE: refractive astigmatism N/A for spherical lenses.
Functionality	Same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Indications	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Production Method	Fully-molded (lathe-cut for specified powers outside +/- 10.00 D)	Fully-molded (lathe-cut for specified powers outside +/- 10.00 D)
USAN name	polymacon	polymacon
Water Content (%)	38±2%	38±2%
Oxygen Permeability	12.48×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	12.48×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)
Specific Gravity	1.17 (hydrated)	1.17 (hydrated)