

510 (K) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS**FOR****SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear****Submitter Information:**

Company: INNOVA VISION INC.
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General manager

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Date Prepared 10 Sep, 2003

Identification of Device:

Classification Name: Soft hydrophilic contact lens, per 21 CFR. 886.5925

Trade Name: SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear

Common or usual Name: Soft Contact lens

FDA Classification: Class II

Predicated Device:

Optima FW™ (polymacon) Visibility Tinted Contact Lenses (NDA number N16895/S087) & SeeQuence (polymacon) Contact Lens for Daily Wear made from Bausch & Lomb Inc.

Indications for Use:

SuperView (polymacon) soft (hydrophilic) contact lens for daily wear is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopia (nearsighted) and may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The eye care practitioner may prescribe the contact lens for frequent replacement wear, with cleaning, rinsing and disinfection and scheduled replacement. The contact lens may be disinfected using heat (not chemical), hydrogen peroxide, or chemical (not heat) disinfection system.

Description of Device:

SuperView (polymacon) soft (hydrophilic) contact lens for daily wear with water content (38.5%) when immersed in a sterile saline solution. It

consists of a polymer of 2-hydroxyethyl methacrylate (HEMA) crosslinked with Ethylene Glycol Dimethacrylate (EGDMA) served as crosslinker. The lenses are produced by spin-casting method to form non-spherical flexible surface, which covers the cornea. The SuperView Contact lens with visible tint is tinted blue using C.I Reactive blue 19 to make the lens more visible for handling. Lenses are supplied sterile in sealed blister PP cup containing isotonic phosphate buffered saline solution. The compatibility and package integrity of the blister cup packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave.

Summary of Clinical Study:

The SuperView lenses were test in 60 human eyes separately within 6 months. Nearly a hundred percent of the participants' vision was corrected and nearly all were satisfied with the lens wearing and care of lenses. The ophthalmologists concludes, based on the specified clinical protocol, that the achieved report demonstrates the SuperView Lenses are safe and effective means of daily wear vision correction and make sure they are a good fit for the human eyes.

Furthermore, SuperView lenses have been wide-used around the world, including Taiwan, China, Europe, Japan, etc. Among the users being daily worn the SuperView lenses, all the procedure was in generally stable condition without severe complication to be observed.

Nonclinical Studies:

A series of non-clinical performance tests were performed to demonstrate the safety and effectiveness of the SuperView Soft Contact lens, and establish substantial equivalence to currently marketed predicate lenses- **Optima FW™ (polymacon) Visibility Tinted Contact Lenses (NDA number N16895/S087)** & SeeQuence (polymacon) Contact Lens for Daily Wear made from Bausch & Lomb Inc. The evidence of substantial equivalent to the predicate lens described as follow:

a) Technological characteristics studies

SuperView lenses designs in the following parameter ranges:

Diameter range; 13.7 to 14.1 mm

Power range: Plano to -12.00D

Center thickness: varies with power (0.08 to 0.12 mm for -3.00D)

Lenses have the following properties:

Refractive index: 1.437 (hydrated)

Light transmittance: >93%

Water content: 38.5 %

Oxygen permeability (edged corrected) : 8.6×10^{-11} [(cm²/sec)(ml O₂/ml-mmHg)] @ 35°C

These characteristics of SuperView Contact lenses are equivalent and comparable to that of predicate lenses.

b) Biocompatibility

In accordance with the May 1994 Guidance Document for daily wear contact lenses, toxicity studies have been conducted on the model: SuperView Contact lens. The Irritation test in the rabbit eye and Systemic toxicity studies in the mouse indicate the extracts would be considered as non-toxic, nor irritated. The Cytotoxicity inspect demonstrates the lens is not cytotoxic under the conditions of the study.

c) Microbiology

The lens sterilization process, steam sterilization, has been validated to deliver a minimum SAL of 10⁻⁶, thereby meeting the requirement of FDA Group I. There is shelf-life stability data supporting that the lens remains sterile through the three years of expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and additive residues.

Substantial equivalence Statement:

Testing performed on the SuperView (polymacon) soft (hydrophilic) contact lens for daily wear indicated that it can support the efficiency and safety use as well as the predicate devices- **Optima FW™ (polymacon) Visibility Tinted Contact Lenses (NDA number N16895/S087)** & SeeSequence (polymacon) Contact Lens for Daily Wear made from Bausch & Lomb Inc., when used in accordance with the instructions for use. It is due to the facts that both fall into the same FDA material classification grouping (Group 1), USAN name (Polymacon), intended use, and efficiency & safety. In conclusion, it is Innova's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, the SuperView soft contact lens with the same established safety profile and effectiveness as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

INNOVA VISION, Inc.
c/o Ms. Jennifer Reich
3892 South America West Trail
Flagstaff, AZ 86001

Re: K033136

Trade/Device Name: SuperView (polymacon) 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: December 11, 2003
Received: January 29, 2004

Dear Ms. Reich:

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 STATEMENT

510(k) Number: K033136

Device Name: SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Innova Vision, Inc.

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K033136


Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter _____