APR 26 2005

K050157

SUMMARY OF SAFETY AND EFFECTIVENESS

FOR MAXSIGHT™ (polymacon) Sport-Tinted Contact Lens

1. Submitter Information:

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Lisa Graney
Manager, Global Regulatory Affairs
Telephone No.: (585) 338-6612
Fax No.: (585) 338-0702

2. Device Name:

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: MAXSIGHT (polymacon) Sport-Tinted Contact Lens

3. Predicate Device:

NaturalTint® (polymacon) Contact Lens N16-895

4. DESCRIPTION OF DEVICE

The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. It consists of a polymer of Hydroxyethyl Methacrylate (HEMA) and crosslinked with Ethyleneglycol Dimethacrylate (EGDMA), and is 38% water by weight when immersed in a sterile saline solution. This lens is tinted in monomer with Reactive Blue Dye 246 (1, 4-Bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone), which conforms to 21 CFR Part 73.3106. Finished lenses are subsequently tinted to achieve different colors using permanently listed color additives that conform to 21 CFR Part 73.3121.

The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is designed to aid visual performance in athletic settings. MAXSIGHT (polymacon) Sport-Tinted Contact lenses enhance contrast in a wide range of outdoor light conditions. This enables the wearer to see a ball or selected objects with greater clarity than with the naked eye.

The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is manufactured with the following dimensions:

Diameter:	13.5 to 15.5 mm
Center Thickness:	0.06 to 0.175mm
Base Curve:	8.4-9.0mm
Powers (Spherical):	+20.00D to –20.00D

The physical / optical properties of the lens are:

Specific Gravity:	1.13
Refractive Index:	1.43
Light Transmittance:	≥30%
UV Absorption:	>95%
UVA absorption:	>95%
UVB absorption:	>95%
Water Content:	38.6%
Oxygen Permeability (Dk):	$8.4_{x10^{-11}}$ [cm^3O_2 (STP) x cm]/(sec x cm^2 x mmHg)@35°C (Polargraphic Method)

Each MAXSIGHT (polymacon) Sport-Tinted Contact Lens is supplied in a plastic blister container with a saline solution. The lid of the container is marked with the base curve, sphere power, diameter, manufacturing lot number, and expiration date.

5. INDICATIONS FOR USE

The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00 to -20.00 diopters. The MAXSIGHT (polymacon) Sport-Tinted contact lens helps protect against the transmission of harmful UV radiation to the cornea and into the eye.

Replacement schedules may vary from patient to patient, and should be decided by eye care professionals in consultation with their patients. The lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professionals. The lens may be disinfected using a chemical disinfection system.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of non-clinical laboratory tests was performed to demonstrate the safety and effectiveness of the MAXSIGHT (polymacon) Sport-Tinted Contact Lens. A summary of results of these tests are provided below.

Safety: Non-Clinical Laboratory Testing

A series of *in vitro* and *in vivo* toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens device. Testing was performed in accordance with FDA guidance *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994.* All non-clinical laboratory studies were conducted in compliance with the GLP regulation.

The results of the testing of the MAXSIGHT (polymacon) Sport-Tinted Contact Lenses demonstrate that:

- The physicochemical properties of the MAXSIGHT (polymacon) Sport-Tinted Contact Lens are equivalent to the predicate device, Bausch & Lomb NaturalTint (polymacon) Contact Lens.

- The physicochemical properties of the MAXSIGHT (polymacon) Sport-Tinted Contact Lens are equivalent to the base lens prior to tinting.

- The extracts of the MAXSIGHT (polymacon) Sport-Tinted Contact Lens do not show any detectable quantities of monomer components, cross-linker, initiator, or diluent. The levels of extracts of the dye are less than 10 ppm, and cytotoxicity testing results of the MAXSIGHT (polymacon) Sport-Tinted Contact Lens demonstrated no toxicity or irritation.

- The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is compatible with several different chemical disinfection systems.

Substantial Equivalence

The MAXSIGHT (polymacon) Sport-Tinted Contact Lens is similar to the Bausch & Lomb NaturalTint (polymacon) Contact Lens, in that both:

- Fall into the same FDA material classification group (Group I),
- Have the same USAN name (polymacon)
- Are manufactured by the same visibility tinted lens manufacturing process (Spin-cast/Lathe cut with in monomer visibility tinting)
- Have equivalent lens color tinting processes; both processes involve tinting a fully cured soft contact lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 26 2005

Ms. Lisa C. Graney
Manager, Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

Re: K050157
Trade/Device Name: MAXSIGHT™ (polymacon) Sport-Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 31, 2005
Received: April 1, 2005

Dear Ms. Graney

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,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known): K050157

Device Name: MAXSIGHT™ (polymacon) Sport-Tinted Contact Lens

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

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

510(k) Number K050157