# SPECIAL 510(k) SUMMARY

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:** K052606

**Applicant information:**

| | |
|---|---|
| Date Prepared: | September 19, 2005 |
| Name: | **Marietta Vision** |
| Address | 397 N. Sessions Street<br>Marietta, GA 30060 |
| Contact Person: | John Patterson |
| Phone number: | 770 792 0208 |
| FDA US Agent/<br>Official Correspondent: | Medvice Consulting, Inc.<br>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: | **Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens.** |

**Unmodified Predicate Devices:**

The **Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens** is substantially equivalent to Marietta Vision's own unmodified predicate devices:

1. **Addvantage 38** (Polymacon), K942302, Marietta Vision.
2. **Marietta Contact Lens, color enhanced**, K002647, Marietta Vision.

**Description of Modified Device:**

The **Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens** is available as a single vision spherical lens. 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 normal buffered saline solution.
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.

As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound color additives. The manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The color additive effect is formed by reacting one or more of the color additives listed in this paragraph with (poly hydroxyethyl methacrylate). The reactive color additives that may be used either alone or in combination are: reactive black 5, reactive blue 21, reactive blue 19, reactive blue 4, reactive blue 163, reactive red 11, reactive red 180, reactive yellow 15, reactive yellow 86, or reactive orange 78. 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 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 (tinted)** | greater than 90% |
| **Water Content** | 38 % ± 2% |
| **Oxygen Permeability** | $8.4 \times 10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg @ 35°C), (revised Fatt method). |

**Intended Use:**

The **Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens** 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 to enhance and/or alter the apparent eye color. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

**Technological Characteristics Comparison:**

The technological characteristics of the **Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens** as compared to the technological characteristics of the unmodified predicate devices are illustrated in the following table.

| Technological Characteristic / Device | Marietta Contact Lens (polymacon), Tinted Daily Wear Contact Lens Modified Device | Addvantage 38 (polymacon), Unmodified Device K942302 | Marietta Contact Lens Color Enhanced, Unmodfied Device K002647 |
|---|---|---|---|
| **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. | Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. | Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. |
| **Functionality** | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. | 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 | Daily wear, Soft (hydrophilic) contact lens |
| **Production Method** | Lathe-Cut | Lathe-cut | Lathe-cut |
| **FDA Group #** | Group # 1 < 50% Water, non-ionic Polymer | Group # 1 < 50% Water, non-ionic Polymer | Group # 1 < 50% Water, non-ionic Polymer |
| **USAN name** | polymacon | polymacon | polymacon * |
| **Water Uptake(%)** | 38.0% | 38.0% | 38.0% * |
| **Sterility of Device** | SAL = $10^{-6}$ | SAL = $10^{-6}$ | Non-sterile product |

* Unmodified device is approved for all soft hydrophilic lenses (not applicable for silicone hydrogels)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2005

Marietta Vision
C/O Mr. Martin Dalsing
Medvice Consulting, Inc.
2214 Sanford Dr. Suite #B7
Grand Junction, CO 81505

Re: K052606
Trade/Device Name: Marietta (polymacon) Tinted Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: November 11, 2005
Received: November 17, 2005

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,

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

# INDICATIONS FOR USE STATEMENT

**Device Name:** **Marietta Contact Lens (polymacon), Tinted Contact Lens.**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Wabuta

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

510(k) Number K052606

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use __

(Optional Format 1-2-96)