NOV 18 1999 K984219

| ***Summary of Safety and Effectiveness Information*** | Color Vision Technologies, Inc. |
|---|---|
| ***Premarket Notification, Section 510(k)*** | NOVEMBER 1999 |

**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**
   **Trade Name:** ColorMax Lens

   **Common Name(s):** Lens, Prescription, Color Deficiency

   **Classification Name(s):** Lens, Prescription, Color Deficiency

2. **Establishment Name & Registration Number:**
   Name: Color Vision Technologies, Inc.
   Number: Pending

3. **Classification(s):**

   §886.5844 **Prescription spectacle lens.** (a) Identification. A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitized.

   (b) Classification. Class 1.

   **Device Class:** 1
   **Classification Panel:** Ophthalmic Devices Panel
   **Product Code(s):** 86NAI

4. **Indication for Use:**
   ColorMax Lenses are indicated for use as an optical aid for Deutan and Protan color vision deficiencies.

5. **Section 514 Compliance**
   Color Vision Technologies, Inc. intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

6. **Special Controls:**
   No special controls apply to this device.

7. **Device Description:**
ColorMax Lenses are colored prescription spectacle lenses that are designed to aid color discrimination performance for those with Deutan and Protan color vision deficiencies. ColorMax Lenses are designed for binocular use. Use of this product may enhance the discrimination of certain colors and may reduce the discrimination of certain colors. This product is not a cure for color vision deficiencies or colorblindness.

8. **Applicant Name & Address:**
Color Vision Technologies, Inc.
19726 Colima Road, Suite 320
Rowland Heights, CA 91748
(714) 730-7900
(714) 730-6800 - fax

9. **Company Contact:**
Ms. Julie Kim
Color Vision Technologies, Inc.
19726 Colima Road, Suite 320
Rowland Heights, CA 91748
(714) 730-7900
(714) 730-6800 - fax

10. **Submission Correspondent:**
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
(925) 356-2640
(925) 356-2654 – fax

11. **Performance Standards:**
United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include U.S.P., ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

12. **Packaging & Storage:**

**Packaging:**
Packaging of the lens blanks should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of damaged product and it should not be used until carefully inspected.

**Storage:**

ColorMax Lenses must be handled, stored and used in such a way that they are protected from inadvertent damage, scratching or other surface contamination.

**13. Summary Basis for Substantial Equivalence of ColorMax Lenses to Prescription Spectacle Lenses:**

ColorMax Lenses are prescription spectacle lenses coated with color filters similar to antireflection coatings and colored prescription sunglass coatings that are already included in the prescription spectacle lens classification. The ColorMax Lenses filters are designed specifically to improve discrimination between colors that are normally confused by people with red-green color vision deficiencies. ColorMax Lenses extend the prescription spectacle lens classification by including optical aid for Protan and Deutan color deficiencies as a new indication for use. Clinical performance studies with the Farnsworth Panel D-15 color vision test have demonstrated the effectiveness of ColorMax Lenses for the new indication by showing that they enable red-green color deficient subjects to distinguish between their usual confusion colors, but reduce their ability to distinguish between some other colors. The potential risks associated with altered color discrimination are comparable for ColorMax Lenses and other tinted prescription spectacle lenses such as colored prescription sunglasses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Ms. Julie Kim
ColorMax Lenses, Inc.
19726 Colima Road
Suite 320
Rowland Heights, CA 91748

Re: K984219
Trade Name: ColorMax Color Vision Enhancement Lenses
Regulatory Class: I
Product Code: 86 NAI
Dated: November 10, 1999
Received: November 10, 1999

Dear Ms. Kim:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** K984219

**Device Name:** ColorMax Lens

**Indications For Use:** ColorMax Lenses are prescription spectacle lenses that are indicated for use as an optical aid for Deutan and Protan color vision deficiences.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K984219

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional format 1-2-96)