K971875

Optim-Eyes 450 Sunglasses
510(k) Summary

JUN 13 1997

1. Device Name

Classification Name: Sunglasses (non-prescription), Class I
Proprietary Name: Optim-Eyes 450 sunglasses

2. Device Sponsor

Taylor/Fox Enterprises, L.L.C.
626 Santa Monica Blvd., Suite 101
Santa Monica, CA 90401
310-624-6277

3. Description of the Device

The Optim-Eyes 450 are non-prescription sunglasses constructed of commonly used materials for sunglass and spectacle frames and lenses.

4. Safety and Effectiveness

All sunglass lots are drop ball tested in accordance with 21 C.F.R. § 801.410.

The lenses meet and exceed current ANSI Z80.3 UV standards for "high and prolonged use", blocking virtually 100% both UVB and UVA radiation. In addition they strongly attenuate short-wave blue light.

4. Substantial Equivalence

The Optim-Eyes 450 sunglasses are substantially equivalent to commercially available sunglass products, including the Blublocker sunglasses (K900382).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Mr. Adam Taylor
Taylor/Fox Enterprises L.L.C.
c/o King & Spalding
1730 Pennsylvania Ave. N.W.
Washington, D.C. 20006

Re: K971875
Trade Name: Optim-Eyes 450 Sunglasses
Regulatory Class: I
Product Code: 86 HQY
Dated: May 5, 1997
Received: May 20, 1997

Dear Mr. Taylor:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 (if known): _____

Device Name: Optim-Eyes 450 sunglasses

Indications For Use:

The Optim-Eyes 450 sunglasses are worn by persons to protect the eyes from bright sunlight, including 100% UVA and UVB, and blue light up to 450 nanometers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
(510(k) Number K971875

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)