3/15/99

K 990606

510(K)
Summary

1. Submitter's Name:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546
Phone: (716) 385-6810
FAX: (716) 889-5688

2. Contact person:

Bonnie Tsymbal
Phone: (716) 264-3210
FAX: (716) 889-5688

3. Date Summary Prepared:

4. Name of Device:

- Trade Name: Preference® standard
  Preference® Toric
  Cooper HT™
  Cooper Toric™
  CV 43™
  Vantage™
  Vantage™ Accents
- Common Name: Soft Contact Lens
- Classification Code: 86LPL
- Classification Name: Lenses, Soft Contact, Daily Wear

5. Legally Marketed Device: Same as Trade Name

6. Description of Device:

All tetrafilcon A Soft (hydrophilic Contact Lenses are hemispherical shells and are available as a spherical or astigmatic lens. When place on the cornea, the hydrated lens acts as a refracting medium to focus light rays on the retina.

The lens material is a hydrophilic random terpolymer of 2-hydroxyethyl methacrylate, N-vinyl-pyrrolidone and methylmethacrylate joined in a three dimensional network of terpolymer chains by divinylbenzene cross links.

When produced with a handling tint, the dye C.I. Reactive Blue 163 is chemically bound to the polymer to impart a light blue tint on the lens. The handling tint increases the visibility of the lens when not worn on the eye.

510(k)
Summary (continued)

7. Intended Use:

Tetrafilcon A lenses are intended for use as a daily wear lens for the correction of refractive ametropia (myopic, hyperopic and astigmatism) in not-aphakic persons with non-diseased eyes.

8. Technological Characteristics:

The technological characteristics of tetrafilcon A lenses manufactured with a in-monomer tint are the same as the predicate device tinted after hydration.

9. Summary of Non-Clinical Tests:

Physical and chemical testing was performed on the lenses made by Aspect using an in-monomer tint as called for in the May 1994 Premarket Notification (510(k) Guidance Document for Daily Wear Contact Lenses. Water content, light transmittance, refractive index and mechanical properties were tested. Toxicity was determined by Cytotoxicity, Ocular Irritation Study and Acute Systemic Study.

10. Conclusion:

The determination of substantial equivalence is based in the results if non-clinical testing. Review of all test data demonstrates that tetrafilcon A lenses manufactured at Aspect Vision, Ltd. with an in-monomer tint, are equivalent to the predicated post-hydration tinted lenses. The in-monomer tinted lenses have the same design, indication and directions for use. CooperVision, Inc. concludes, therefore, that the in-monomer tinted lenses are substantially equivalent to the post-hydration tinted lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Ms. Bonnie Tsymbal
Regulatory Associate
COOPERVISION, Inc.
711 North Road
Scottsville, New York 14546

Re: K990606
Trade Name: The Preference ® Standard, CooperClear ™, CV43 ™, Vantage ® and Vantage ® Accents, (tetrafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (Spherical and Toric, Clear and Handling Tint with In- Monomer-Tinting Process, Cast-molded)
Regulatory Class: II
Product Code: 86 LPL
Dated: February 22, 1999
Received: February 23, 1999

Dear Ms. Tsymbal:

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

CooperVision®
711 North Road
Scottsville, New York 14546
(716) 385-6810
Fax (716) 889-5688

Indications for Use Statement

510(k) Number: K 990606

Device Name: Preference® standard
Preference Toric™
Cooper Toric™
CooperHT™
CV 43™
Vantage®
Vantage® Accents

Indications for Use:

The Preference® standard, CooperClear™, CooperHT™, CV 43™, Vantage® and Vantage® Accents (tetrafilcon A) Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity by not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses can be worn by persons who exhibit astigmatism of 2.50 diopters or less that does not interfere with visual acuity.

The PreferenceToric™ and Cooper Toric™ hydrophilic contact lenses are indicated for daily wear use by not-aphakic persons with non-diseased eyes that are myopic or hyperopic, who exhibit astigmatism up to 9.00 diopters and can obtain satisfactory visual acuity, in a spherical range of –20.00 to +12.00.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or Over-the-Counter Use** _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 990606