510(K) Summary
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NOV 24 1999

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

K993252

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: October 5, 1999

4. Name of Device:

- Trade Name:

Frequency 55
Frequency 55 UV
Frequency 55 Aspheric
Encore
Encore Toric
CooperFlex
Onevue

- Common Name: Soft Contact Lens

- Classification Name: Soft Hydrophilic Contact Lens
(Per 21 CFR §886.5925)

5. Legally Marketed Device: Same as Trade Name

6. Description of Device:

Frequency 55, Frequency 55 Aspheric, Encore, CooperFlex and Onevue (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. Encore Toric (methafilcon A) Soft (hydrophilic) Contact Lenses are available as astigmatic (toric) lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are tinted from edge to edge for visibility purposes with the color additive, Reactive Blue No. 4.

Frequency 55 UV (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. A benzotriazole UV absorbing monomer is used to block UV radiation. the average transmittance characteristics are less than 10% in the UVB range if 280 t0 315 nm and less than 10% in the UVA range of 315 to 380 nm. The lenses are tinted aqua from edge to edge for visibility purposes with the color additives, C.I. Reactive Blue No. 4 and C.I. Reactive Yellow 86.

7. Intended Use:

Methafilcon 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:

Design, material, and chemical composition are unchanged from those cleared in K971164, K973063, and K982997.

9. Summary of Non-Clinical/Clinical Tests:

No Non-Clinical or Clinical tests were performed. The lenses are the same as those cleared in the above premarket notifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Ms. Bonnie Tsymbal
Coopervision, Inc.
711 North Road
Scottsville, NY 14546

Re: K993252
Trade Name: Frequency 55, Frequency 55 UV, Frequency 55 Aspheric, Encore, Encore Toric, CooperFlex and Onevue (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear
Regulatory Class: II
Product Code: LPL, MVN (Disposable Use)
Dated: November 5, 1999
Received: November 8, 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 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). 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

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.

Indication for Use Statement

510(k) Number: K993252

Device Name: Frequency 55
Frequency 55 UV
Frequency 55 Aspheric
Encore
Encore Toric
CooperFlex
Onevue

Indications for Use:

1. Frequency 55, Frequency 55 UV, Frequency 55 Aspheric, Encore, CooperFlex and Onevue are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with usual acuity.

   Frequency 55 lenses with UV absorbing monomer helps protect against transmission of harmful UV radiation to the cornea and into the eye.

2. Encore Toric lenses are indicated for daily for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Frequency 55, Frequency 55 Aspheric, Frequency 55 UV, Encore, Encore Toric, CooperFlex and Onevue lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitoner.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

Prescription Use _____
(Per 21 CFR 801.109)

_____
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993252