DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Mr. Bernard F. Hallatt
Manager, Quality Assurance and Regulatory Affairs
CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Re: K963013
Trade Name: Envoy and Envoy Toric (epsifilcon A) Contact Lenses
(clear and visibility tint with a molded back surface and a lathe cut front surface)
Regulatory Class: II
Product Code: 86 LPL
Dated: October 7, 1997
Received: October 8, 1997

Dear Mr. Hallatt:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 Devices 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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: K963013

Device Name: Enovy
Envoy Toric

Indications for Use:

The Envoy and Envoy Toric (epsifilcon A) Contact Lenses are indicated for daily wear by not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lenses may be worn by persons who exhibit astigmatism of 2.50 diopters or less, the toric lens by persons with astigmatism of 9.00 diopters.

(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** _____

Daniel W. C. Brown PhD
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K963013