DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1997

Benz Research and Development Corporation, Inc.
c/o Wally Sterling
South East Regulatory Associates, Inc.
235 North Talbot Court
Roswell, GA 30076-2480

Re: K972807
Trade Name: BENZ Hefilcon A Soft (Hydrophilic) Daily Wear Contact Lenses (Clear, and Blue or Light-Green Visibility Tinted, Lathe-Cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: July 25, 1997
Received: July 28, 1997

Dear Mr. Sterling:

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:

Device Name: BENZ hefilcon A Spherical and Toric Contact Lenses in clear and with light blue or light green visibility tint for Daily Wear

SECTION 7 INDICATIONS for USE

The BENZ hefilcon A SPHERICAL Soft (Hydrophilic) Contact Lenses in clear or with a light blue or light green visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes. The spherical lenses are available from +20.00 to -20.00 Diopters and may be worn by patients who can accomodate up to 1.5 Diopters of astigmatism.

The BENZ hefilcon A TORIC Soft (Hydrophilic) Contact Lenses in clear or with a light blue or light green visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes. The Toric lenses are available from +20.00 to -20.00 Diopters and up to 4.50 Diopters of astigmatic correction where it does not interefere with visual acuity.

The BENZ hefilcon A Spherical and Toric Contact lenses may be disinfected using either the heat (thermal) or the chemical (non-heat) disinfection system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mynn Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972807

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96