K980418

SUMMARY STATEMENT OF SAFETY & EFFECTIVENESS FEB 27 1998

Soft (hydrophilic) contact lenses for Daily Wear manufactured from methafilcon A material are generally recognized as safe and effective. Such lenses have been successfully marketed in the U.S. since the early 1980's by several manufacturers of both optical blanks and finished lenses. To date, there are more than twelve approved methafilcon A products (PMA's & 510(k)'s) on the U.S. market.

To demonstrate the methafilcon A material manufactured by BENZ R&D and the finished lenses manufactured from BENZ methafilcon A is safe and effective for its intended use, we offer the following statements:

1. PURPOSE OF THIS NOTIFICATION

BENZ's primary interest is in the distribution of optical blanks. They will manufacture and test a limited number of finished lenses for Quality Assurance and customer support purposes. The methafilcon A blanks will only be sold to finishing laboratories with the appropriate regulatory approvals for the distribution of methafilcon A contact lenses.

2. DEVICE DESCRIPTION

The BENZ methafilcon A soft (hydrophilic) spherical and toric contact lenses will be made from clear methafilcon A optical blanks and indicated for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes to be worn in daily wear regimens.

The spherical lenses are available from +20.00 to -20.00 diopters and will mask up to 1.50 diopters of astigmatism where it does not interfere with visual acuity.

The toric lenses are available from +20.00 to -20.00 diopters and with up to 4.50 diopters of astigmatic correction.

The BENZ methafilcon A optical blanks are lathed into a soft (hydrophilic) spherical or toric hemispherical shell. The spherical lenses have a spherical base curve and the toric lenses have a non-spherical base curve.

This non-ionic material is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid crosslinked with Ethylene Glycole Dimethacrylate, plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in normal buffered saline solution.

When the lens is hydrated and placed on the cornea it acts as a refracting medium to focus light rays on the retina.

SUMMARY STATEMENT OF SAFETY & EFFECTIVENESS (continued)

3. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures for the same indications are in use and generally consist of other prescription products such as soft or RGP contact lenses made from other materials, or spectacles.

4. TECHNICAL SUMMARY

A. PRE-CLINICAL TESTING

The following pre-clinical tests were run by a recognized independent testing facility:

i. Primary Ocular Irritation
ii. Systemic Injection
iii. Agar Diffusion

All results obtained were within normal limits hence this material meets the toxicological requirements for Class II contact lenses.

B. PHYSICAL TESTING

The following tests were run to demonstrate the physical properties of the lens material are within normal limits:

i. Burst Test
This test was performed by an independent laboratory and demonstrates the physical strength of the material is within normal limits.

ii. 12 Lens Parameter Test
The Power; Diameter; and Base Curve Radius was measured on 12 lenses made from BENZ methafilcon A optical blanks. The measurements obtained on the lenses when measured were within normal limits.

C. FINISHED LENS TESTING

All lenses to be produced form BENZ methafilcon A will be manufactured in accordance with the methods, equipments, and facilities documented in the referenced 510(k) Notification K950294 Flexlens 55 (methafilcon A) Soft Contact Lenses.

SUMMARY STATEMENT OF SAFETY & EFFECTIVENESS (continued)

Please refer to K950294 for the following information for all BENZ methafilcon A lenses:

i. Microbiology
ii. Solutions Compatibility
iii. Shelf Life/Stability
iv. Preservative Uptake/Release

A letter of authorization to reference this 510(k) is included with this Notification.

Flexlens last FDA inspection was March 7, 1996 and there are no outstanding GMP deficiencies.

5. CONCLUDING STATEMENTS

Any adverse effects to the patient would not be any more likely or any more severe with lenses made from BENZ methafilcon A than with lenses made from any other methafilcon A or any other soft contact lens material.

From the above referenced test data, it can be deduced that the BENZ methafilcon A material is safe and effective for its intended purpose as a daily wear contact lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael A. Clark
Consultant to BENZ
c/o South East Regulatory Associates, Inc.
1070 Thornwood Lane
Dacula, GA 30019

FEB 27 1998

Re: K980418
Trade Name: BENZ methafilcon A Spherical and Toric Soft (hydrophilic) contact lenses (clear, lathe cut) for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: January 30, 1998
Received: February 3, 1998

Dear Mr. Clark:

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 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 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

INDICATIONS FOR USE

The BENZ methafilcon A soft (hydrophilic) spherical and toric contact lenses will be made from clear methafilcon A optical blanks and indicated for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes to be worn in daily wear regimens.

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The lenses may be disinfected using chemical disinfection systems.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W.C. Brown, Ph.D. JS

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980418

Prescription Use X OR Over the Counter Use _____

(Optional Format 1-2-96)