

MAR 11 1997

SUPPLEMENT to K964902 METRO-G 3X (hioxifilcon B) JAN. 20. 1997

6.0 SUMMARY of SAFETY AND EFFECTIVENESS

I. General Information:

- A. Generic (USAN) Name: hioxifilcon B
- B. Device Trade Name: METRO-G 3X (hioxifilcon B)  
Spherical and Toric Soft  
(Hydrophilic) Contact Lenses for  
Daily Wear in Clear and with a Blue  
Visibility Tint
- C. Sponsor's Name and  
Address: METRO OPTICS of AUSTIN, INC.  
15802 Vision Drive  
Pflugerville, TX 78660  
(800) 223-1858
- D. 510(k) Number: K964902

II. Indications

METRO-G 3X Spherical (hioxifilcon B) soft (hydrophilic) contact lenses made from BENZ-G 3X (hioxifilcon B) optical blanks in clear or a blue visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and/or non-aphakic persons with with non-diseased eyes. The Spherical lenses are available from +20.00 to - 20.00 Diopters for persons with up to 1.50 Diopters of astigmatism where the astigmatism does not interfere with visual acuity.

METRO-G 3X Toric (hioxifilcon B) soft (hydrophilic) contact lenses made from BENZETRO-G 3X (hioxifilcon B) optical blanks in clear or blue visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and non-aphakic persons with 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.

The material, BENZ-G 3X (hioxifilcon B), is a non-ionic polymer that may be disinfected using either the heat (thermal) or the chemical (not heat) disinfection system.

III. Device Description

METRO-G 3X (hioxifilcon B) Spherical or Toric is lathed into a soft (hydrophilic) contact lens which is a hemispherical shell. The Toric has a Toric Base Curve. The non-ionic material, hioxifilcon B is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA).

The copolymer consists of 52% METRO-G 3X (hioxifilcon B) and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

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The lens METRO-G 3X (hioxifilcon B) is made from BENZ-G 3X (hioxifilcon B) optical buttons. When the lens is hydrated and placed on the cornea it acts as a refracting medium to focus light rays on the retina.

BENZ-G 3X (hioxifilcon B) optical buttons with visibility tint were subjected to extraction studies and showed no identifiable evidence of tint pigment leeching.

### IV. Alternative Practices or Procedures

Alternative practices or procedures are in the use of available prescription products Soft and RGP Contact Lenses and spectacles for the same indication.

### V. Technical Summaries

#### A. Pre Clinical

##### 1. Toxicology

Toxikon ran all pre-clinical studies necessary for review for Class II daily wear soft (hydrophilic) contact lenses. Results were within normal limits.

##### 2. Microbiology

Relevant studies have been run and are included with this 510(k) notification. This includes autoclave validation.

##### 3. Lens compatibility studies were run by the developer of the polymer and are referenced in his 510(k) Notification.

Conclusion: Within Normal Limits

##### 4. Lens Stability The Shelf life studies have been started by Metro Optics of Austin, Inc. and will be complete early in 1997. The procedure is based on sample supplied by FDA in Guidance Document for 510(k) for Daily Wear Contact Lenses, May 1994. Study will be completed in late January 1997 to assure sterility to the one year duration. No product will be distributed until tests are complete and the FDA has approved manufacture and distribution.

##### 5. Preservative Uptake Tests were run by ALCON and were referenced by the developer of the polymer in his 510(k).

Results were within normal limits.

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This application includes application for Heat and Chemical (Not Heat) disinfection as the polymer as the polymer is Non-ionic. In house tests showing that heat has no injurious effect on the lenses made of this polymer.

This summary of safety and effectiveness enclosed covers the hioxifilcon B lathe-cut lens made by METRO OPTICS of AUSTIN, INC.

A favorable recommendation from the FDA for the METRO-G 3X (hioxifilcon B) Spherical and Toric Contact Lenses made from BENZ-G 3X (hioxifilcon B) optical blanks in clear or with blue visibility tint for daily wear use is anticipated. We feel that a review of notification will show that this polymer is close enough to the approved METRO-G 55 (5X) (hioxifilcon A) (48% water as opposed to 58% water). The METRO-G 55 (5X) was both safe and effective for its intended purpose of a daily wear contact lens.

Should additional information be desired, please contact Wally Stirling, South East Regulatory Associates, Inc. 770-475-1668.