

K 961606

Supplement to K961606 METRO FOCAL 38 ASPHERIC (polymacon) Soft
(Hydrophilic) Contact Lenses for Daily Wear AUG. 28, 1996

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SECTION 8 SUMMARY of SAFETY AND EFFECTIVENESS

I. General Information:

- A. Generic (USAN) Name: polymacon
- B. Device Trade Name: METRO FOCAL 38 ASPHERIC (polymacon)
- C. Sponsor's Name and Address: METRO OPTICS of AUSTIN, Inc.
15802 Vision Drive
Pflugerville, TX 78660
(512) 251-2382
- D. 510(k) Number: K961606

II. Indications

The METRO FOCAL 38 ASPHERIC (polymacon) soft (hydrophilic) contact lenses for daily wear are available in clear and with a blue visibility tint. The lenses are indicated for visual acuity in non-aphakic patients with with non-diseased eyes. The lenses are available in powers of -20.00 up to +10.00 Diopters of and up to 2.50 Diopters of add. These lenses will mask 2.00 Diopters of astigmatism where it does not interfere with visual acuity.

III. Device Description

The METRO FOCAL 38 ASPHERIC (polymacon) soft (hydrophilic) contact lenses are lathe cut into an aspherical contact lens geometry which becomes a hemispherical shell. The polymer, polymacon was the first soft (hydrophilic) material and is one of the most frequently used polymers of HEMA at this time. It consists of 62% polymacon and 38% water by weight when fully hydrated in normal saline solution buffered with sodium bicarbonate.

The METRO FOCAL ASPHERIC (polymacon) soft (hydrophilic) contact lenses when hydrated and placed on the cornea acts as a refracting medium to focus light rays on the retina.

IV. Alternative Practices or Procedures

Alternative practices or procedures are in the use of available prescription products soft (hydrophilic) contact lenses, RGP or Rigid Gas Permeable contact lenses or spectacles.

V. Technical Summaries

A. Pre Clinical

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1. Toxicology

This had been run on the polymer (polymacon) and included in another submission. Results were within normal limits.

2. Microbiology

Included in same submission as above Toxicology results. Results were within normal limits.

3. Compatibility

This had been run on this polymacon polymer in 1990. Results were within normal limits.

4. Stability

This had been run on the polymer polymacon in another submission in 1990. Results were within normal limits. Metro Optics has on-going stability studies validating the expiration date of four years at this time for the clear and a lesser time for the blue visibility tint

5. Preservative Uptake Tests

This had been run on polymer polymacon in another submission in 1990. Results were within normal limits.

B. Clinical

The Sponsor is referencing the fact that there are eighteen Contact Lens companies producing aspheric contact lenses for the correction of presbyopia. Thirteen of these lenses are made from the same polymer, polymacon, as is the lens in question. All these lenses are generated on similar equipment in a similar manner. The equipment manufacturers of lathes, autoclaves, laminar flow units, polishing equipment may be different between any two companies however the end contact lens products are for all intents equivalent.

The manufacturing materials, manufacturing methods, and quality control methods employed by most companies are equivalent. The results are all approximately the same.

This contact lens manufacturing facility has been producing soft (hydrophilic) contact lenses for over fourteen years and was last inspected by the FDA on October 8, 1993

C. Potential Safety and Effectiveness as well as Adverse Effects of the Device would be about the same as that of any other aspheric polymacon lens.

D. Conclusion drawn from Study

This lens should be the equivalent of any other lens of aspheric configuration.

E. A favorable recommendation from the FDA is anticipated for the manufacture and distribution of aspheric soft (hydrophilic) contact lenses made by Metro Optics of Austin, Inc. Any additional information will be supplied by the individual whose name and address is on the cover letter of this 510(k) Notification.