

K961163

AUG 23 1996

SUMMARY of SAFETY AND EFFECTIVENESS

I. General Information:

- A. Generic (USAN) Name: polymacon
- B. Device Trade Name: BENZ 38 Clear and Visibility Tinted optical buttons and BENZ 38 Lenses Clear and Visibility Tinted
- C. Sponsor's Name and Address: Benz Research and Development, Inc.  
6447 Parkland Drive  
Sarasota, FL 34243  
(813) 758-8256
- D. 510(k) Number: TO BE ASSIGNED
- E. Date Notice of approval sent to Sponsor:
- G. Additional Lens manufacturers who will be asking for FDA approval to manufacture and distribute soft (hydrophilic) contact lenses made from BENZ 38 will file a separate 510(k) notification. The first will be:

UNILENS CORP., USA  
10431 - 72nd Street North  
Largo, Florida 34543  
(813) 544-2531

II. Indications

BENZ 38 (polymacon) Spherical soft (hydrophilic) contact lenses in clear or with blue visibility tint form are indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with with non-diseased eyes. The spherical lenses are being applied for from +12.00 to -20.00 Diopters and masking up to 1.50 Diopters of astigmatism where it does not interfere with visual acuity.

BENZ 38 (polymacon) Toric soft (hydrophilic) contact lenses in clear or with blue visibility tint form are also indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with with non-diseased eyes. The spherical lenses are being applied for from +12.00 to -20.00 Diopters up to 4.50 Diopters of astigmatism where it does not interfere with visual acuity.

III. Device Description

BENZ 38 (polymacon) lens can be lathed into a spherical soft (hydrophilic) contact lens which becomes a hemispherical shell. The non-ionic material, hioxifilcon A is an ultra high molecular weight homo-polymer of 2-hydroxyethyl methrylate (2-HEMA). This material is made from extremely

high purity monomer using state of the art polymer synthesis technique. It consists of 62% hioxifilcon A and 38% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

The lens made from BENZ 38 (polymacon) when hydrated and placed on the cornea acts as a refracting medium to focus light rays on the retina. BENZ 38 with the visibility tint was subjected to leeching tests and showed no identifiable evidence of leeching.

The clear BENZ 38 (polymacon) optical buttons are identical to the polymacon optical buttons made by Benz Research and development in PMA P830012/S04 approved June 5, 1990. The pigment used in the BENZ-38 Blue Visibility tinted buttons and in BENZ-38 blue visibility tinted lenses is identical to the pigment used in K952620 BENZ-G 55 (hioxifilcon A) Class II Soft(hydrophilic) contact lenses Class 86-LPL, approved DEC. 1, 1995.

#### IV. Alternative Practices or Procedures

Alternative practices or procedures are in the use of available prescription products with the same indication.

#### V. Technical Summaries

##### A. Nonclinical

##### 1. Toxicology

BENZ RESEARCH AND DEVELOPMENT, INC. ran all pre-clinical studies for the clear lenses in 1990 and for the blue visibility tinted product in 1995 (submitted with this notification).

Conclusion: Clear Approved 1990. Test results on Blue Visibility tinted product are within the same acceptable limits.

##### 2. Microbiology

We are submitting all microbiology work done by Unilens Corp. USA. in 1995 using a validated process.

Conclusion: Clear approved in 1990

##### 3. Lens compatibility studies run by BENZ Research and Development included with this Notification in "Lens Compatibility Studies"

Conclusion: Within Normal Limits

##### 4. Lens Stability The Shelf life will be run by each lens manufacturing unit. Our lenses were sterilized at Unilens Corp. USA and we are asking for the same expiration date as they will. The results are listed under Shelf Life.

have to make it's own protocol for this study and apply for an individual shelf life.

5. Preservative Uptake Tests were run by on the original BENZ 38 material for P830012/S04 approved June 5, 1990.

Results are within normal limits.

#### B. Clinical

Clinical Study was done on the original BENZ 38 Clear material for P830012/S04 which was approved June 5, 1990.

Study results fell within normal limits.

BENZ RESEARCH AND DEVELOPMENT, INC. will own the polymer BENZ 38 (polymacon) in clear and visibility tint and is applying to the FDA for permission to have this basic optical polymer approved.

In a separate notification UNILENS, Corp., USA will apply to the FDA to approve their facilities for the manufacture and distribution of soft (hydrophilic) contact lenses made from this polymer BENZ 38 (polymacon).

The equipment manufacturers of lathes, autoclaves, laminar flow units, polishing equipment may be different between those at BENZ Research and Development and the alternate site companies however the end contact lens products are for all intents equivalent.

The manufacturing materials, manufacturing methods, and quality control methods employed by both companies are equivalent.

Benz Research and Development intends to add additional finishing laboratories in the future. These will be the subject of separate 510(k) notifications.

BENZ R&D was last FDA inspected on March 20, 1990

#### VI. RECOMMENDATION

This Notification is based on the previous FDA approval of P830012/S04 on June 5, 1990 and the approval of a similar polymer with the identical pigment for visibility tint in K952620 on Dec. 1, 1995.

A favorable recommendation from the FDA is anticipated for the manufacture and distribution of optical button of BENZ 38 (polymacon) clear and blue visibility tinted as well as the manufacture and distribution of soft (hydrophilic) lenses made from this polymer. Any additional information will be supplied by the individuals who's name and address first appear in this notification.