SUMMARY of SAFETY AND EFFECTIVENESS

K962000

I. General Information:

OCT 1 1996

A. Generic (USAN) Name: methafilcon A

B. Device Trade Name: FLEXLENS 55 (methafilcon A) HARRISON Post Refractive Surgery Lens for Daily Wear

C. Sponsor's Name and Address:
FLEXLENS LLC
3241 South Zuni Street
Englewood, CO 80110
(800) 223-3539

D. 510(k) Number: K962000

II. Indications

The FLEXLENS 55 (methafilcon A) HARRISON Post Refractive Surgery Contact Lens is indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.

III. Device Description

The FLEXLENS 55 (methafilcon A) Harrison Post Refractive Surgery Contact Lens for daily wear is a soft (hydrophilic) contact lens with a spherical or toric base curve and a spherical front surface. The lens is lathe cut from methafilcon A, a random copolymer of 2-hydroxyethyl methacrylate and methacrylic acid crosslinked with ethylene glycol dimethacrylate. It consists of 45% methafilcon A and 55% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

The physical properties of the lens are as follows:

* Refractive Index: 1.4153
* Light Transmittance: greater than 95%T
* Water Content: 55%
* Oxygen Permeability: $Dk=18 \times 10^{-11}$ at 35 °C (measured by the standard Fatt method)
* Specific Gravity: 1.090 g/cc

The FLEXLENS 55 (methafilcon A) Harrison Post Refractive Surgery Contact Lens for daily wear was developed to improve the visual acuity of those patients who require improved vision after photorefractive keratectomy, radial keratotomy, and other corneal refractive procedures. Other factors taken into consideration were the following:

1. The topographical profile is such that it is difficult to achieve a satisfactory posterior lens surface to cornea alignment with rigid gas permeable contact lenses.

2. Conventional soft (hydrophilic) contact lens designs do not readily align with the visual axis of the PRS or RK eye or supply sufficient masking of the corneal astigmatism.

3. Conventional toric soft (hydrophilic) contact lenses are limited in their ability to provide a stable level of visual acuity on cases of extreme central flattening in conjunction with irregular astigmatism.

The Harrison Post Refractive Surgery Lens differs from the standard spherical FLEXLENS Custom Sphere in that it incorporates a flat central optical zone with a thickness which varies with power (-1.00D will be approximately 0.30mm thick at the center). The size of the optical zone is generally 8.0mm. The peripheral carrier is thinner than most standard soft (hydrophilic) contact lenses, approximately 0.08mm to 0.10mm, to ensure limbal draping which will exhibit the characteristics (on the eye) of a peripheral aspheric design. In some cases the periphery is manufactured with a steeper curvature than the base curve.

IV. Alternative Practices or Procedures

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

V. Technical Summaries

A. Pre Clinical

1. Toxicology

This was run on methafilcon A the FLEXLENS original 510(k) K950294 approved by FDA 04/11/1996

2. Microbiology

This was run on methafilcon A for the FLEXLENS original 510(k) K950294 approved by the FDA 04/11/1996

3. Compatibility

This was run on methafilcon A for the FLEXLENS original 510(k) K950294 approved by the FDA 04/11/1996

4. Stability

This was run on methafilcon A for the FLEXLENS original 510(k) K950294 approved by the FDA 04/11/1996.

Presently we are have the shelf life at 2 years.

5. Preservative Uptake Tests

This was run on methafilcon A for the FLEXLENS original 510(k) K950294 approved by the FDA 04/011/1996

B. Clinical

The Sponsor is referencing a small clinical study that was run in Canada. These patients had previously been fitted with the FLEXLENS (hefilcon A) HARRISON POST REFRACTIVE SURGERY LENS. These same patients were re-fit with the FLEXLENS 55 (methafilcon A) HARRISON POST REFRACTIVE SURGERY LENS. These patients were fit and a follow-up visit was made at an average of 2.4 months.

Their distribution was 10 patients with 12 eyes. The The principal investigator was Keith W. Harrison, FCLSA The lens was fitted to 6 patients following Photorefractive Keratectomy (PRK), 3 patients following a Radial Keratotomy (RK) and one patient following a a corneal keratoplasty (also aphakic).

The study indicates there was no substantial change from one polymer to the other. Both types of lens were made from identical parameters, the only difference was the water content.

FLEXLENS, LLC's last FDA inspection was completed on March 7, 1996.

C. Potential Safety and Effectiveness as well as Adverse Effects of the Device on Health would be about the same as that of any other methafilcon A daily wear lens.

D. Conclusion drawn from Study

This lens should be the equivalent of any other Flexlens daily wear lens made of methafilcon A.

E. A favorable recommendation from the FDA is anticipated for the manufacture and distribution of FLEXLENS 55 (methafilcon A) HARRISON POST REFRACTIVE SURGERY LENS for Daily Wear. Should any additional information be required, it will be supplied by the individual whose name and address is on the cover letter of this 510(k) Notification.