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Pilkington Barnes Hind Sunnyvale, California	vasurfilcon A (74%) Contact Lenses
	Premarket Notification 510(k) K961299

Summary of Safety and Effectiveness

Indications for Use:

Precision UV™ (vasurfilcon A) Hydrophilic contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 2.00 diopters (D) or less of corneal astigmatism that does not interfere with visual acuity. The contact lenses may be prescribed for daily wear as recommended by the eye care practitioner.

Device Description:

Precision UV™ (vasurfilcon A) soft (hydrophilic) contact lenses are available as clear and locator tinted spherical lenses in the power range from -10.00 to +6.00 diopters, center thicknesses from 0.10 - 0.26 mm (minus lenses) and 0.18 - 0.37 mm (plus lenses) with base curves of 8.4 and 8.7 mm and a diameter of 14.4 mm. The lens material, vasurfilcon A, is a hydrophilic random copolymer of N-vinyl-pyrrolidone (NVP), Methyl methacrylate (MMA), Allyl methacrylate (AMA), Ultraviolet absorbing monomer (UVAM) and AIBN (Azo-Iso-butyronitrile) as an initiator. It consists of 74% water and 26% vasurfilcon A.

Precision UV™ (vasurfilcon A) soft (hydrophilic) contact lenses are currently marketed domestically and internationally by Pilkington Barnes Hind under PMA P940013. Previously, they were marketed by Pilkington Barnes Hind under Allergan Medical Optic's PMA P790020.

Alternate Procedures:

The purpose of this premarket 510(k) notification is to request clearance to tint Precision UV™ (vasurfilcon A) contact lenses using an alternative, non-reactive, light blue-green locator tint (D&C Green No. 6, C.I. No. 61565) in an in-monomer tinting process. On January 24, 1995, PBH received clearance in Premarket 510(k) Notification K946012 to tint molded Precision UV™ (vasurfilcon A) with a light blue locator tint (Vat Blue No. 6, C.I. No. 69825) using a post-lens manufacture tinting process, hereafter referred to as the CTL process. The alternative tinting process will substitute the use of Vat Blue No. 6 dye and the associated CTL process with the use of non-reactive D&C Green No. 6. This alternative tinting process will hereafter be referred to as an in-monomer tint or IMT process. The lens molding manufacturing process will otherwise remain the same as that currently approved. Further, the use of D&C Green No. 6 in tinting Precision UV™ (vasurfilcon A) lenses will be in accordance with color additive listing provisions of 21 Code of Federal Regulations § 74.3206. It should be noted that D&C Green No. 6 has previously been used in tinting contact lenses. Specifically, PBH received approval on December 28, 1990 in Supplement 1 to PMA P890020 for Fluorocon 60 (paflucocon B) daily wear (clear and tinted) contact lenses. Notably, these tinted lenses contained D&C Green No. 6.

A minor labeling change has occurred as a result of the use of D&C Green No. 6 dye. Revised, proposed labeling has been included in Section VII. of this premarket 510(k) notification. The changes are clearly marked on the Package Insert and include only those changes relative to the locator tint description of the lens. The proprietary trade name of the lens, as well as the indications for use, will remain the same as those already identified and approved.

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Summary of Safety and Effectiveness, *continued...*

Summary of Non-Clinical Laboratory Studies:

The alternative IMT tinting process, which substitutes the use of Vat Blue No. 6 dye and the associated CTL process with the use of non-reactive D&C Green No. 6 in the IMT process has been shown to be substantially equivalent, as evidenced by results of the Non-Clinical Laboratory Studies. These laboratory tests fully demonstrate that this process does not affect the substantial equivalence, compatibility, stability or physical functional qualities of the vasurfilcon A lens. Specifically, data has been included which supports 8 months of stability (2 months at 45°C) for Precision UV™ lenses manufactured with the proposed IMT process change. Future testing will continue at room temperature and at 45°C in order to demonstrate stability for 5 years at room temperature.

Clinical Studies:

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the vasurfilcon A (74%) contact lens tinted with the in-monomer tint process using D&C Green No. 6 dye. This determination was based on the following:

- The use of D&C Green No. 6 in tinting Precision UV™ (vasurfilcon A) daily wear hydrophilic soft contact lenses will be in accordance with color additive listing provisions of 21 Code of Federal Regulations § 74.3206.
- The batch acceptance testing and final lens release criteria remain the same. The vasurfilcon A (74%) physical properties were measured and the results were compared to clear, untinted lenses manufactured with the current approved procedures and specifications. Both the clear lenses manufactured by the current approved procedures and the lenses manufactured with current approved procedures and tinted with D&C Green No. 6 dye using the IMT process showed no significant differences and met all product specifications, as demonstrated by the Non-Clinical Laboratory Study results found in Section IV.
- D&C Green No. 6 dye has been previously used in tinting contact lenses. Specifically, PBH received approval on December 28, 1990 in Supplement 1 to PMA P890020 for Fluorocon 60 (paflucocon B) daily wear (clear and tinted) contact lenses. Notably, these tinted lenses contained D&C Green No. 6 dye.
- The approval of Supplement 1 to PMA P890020 substantiates the safe and efficacious use of D&C Green No. 6 dye as a locator tint in Precision UV™ (vasurfilcon A) daily wear hydrophilic soft contact lenses. In light of the established precedent accompanying the approved use of D&C Green No. 6 in tinting contact lenses, as well as the toxicology and clinical data encompassed by Supplement 1 to PMA P890020, additional studies of this nature were not performed.

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Summary of Non-Clinical Laboratory Studies:

The alternative IMT tinting process, which substitutes the use of Vat Blue No. 6 dye and the associated CTL process with the use of non-reactive D&C Green No. 6 in the IMT process has been shown to be substantially equivalent, as evidenced by results of the Non-Clinical Laboratory Studies. These laboratory tests fully demonstrate that this process does not affect the substantial equivalence, compatibility, stability or physical functional qualities of the vasurfilcon A lens. Specifically, data has been included which supports 8 months of stability (2 months at 45°C) for Precision UV™ lenses manufactured with the proposed IMT process change. Future testing will continue at room temperature and at 45°C in order to demonstrate stability for 5 years at room temperature.

Clinical Studies:

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the vasurfilcon A (74%) contact lens tinted with the in-monomer tint process using D&C Green No. 6 dye. This determination was based on the following:

- The use of D&C Green No. 6 in tinting Precision UV™ (vasurfilcon A) daily and extended wear hydrophilic soft contact lenses will be in accordance with color additive listing provisions of 21 Code of Federal Regulations § 74.3206.
- The batch acceptance testing and final lens release criteria remain the same. The vasurfilcon A (74%) physical properties were measured and the results were compared to clear, untinted lenses manufactured with the current approved procedures and specifications. Both the clear lenses manufactured by the current approved procedures and the lenses manufactured with current approved procedures and tinted with D&C Green No. 6 dye using the IMT process showed no significant differences and met all product specifications, as demonstrated by the Non-Clinical Laboratory Study results found in Section IV.
- D&C Green No. 6 dye has been previously used in tinting contact lenses. Specifically, PBH received approval on December 28, 1990 in Supplement 1 to PMA P890020 for Fluorocon 60 (paflucocon B) daily and extended wear (clear and tinted) Rigid Gas Permeable contact lenses. Notably, these tinted lenses contained D&C Green No. 6 dye.
- The approval of Supplement 1 to PMA P890020 also substantiates the safe and efficacious use of D&C Green No. 6 dye as a locator tint in Precision UV™ (vasurfilcon A) daily and extended wear hydrophilic soft contact lenses. In light of the established precedent accompanying the approved use of D&C Green No. 6 in tinting contact lenses, as well as the toxicology and clinical data encompassed by Supplement 1 to PMA P890020, additional studies of this nature were not performed.