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510(k) Summary
for the
Menicon Z™ Rigid Gas Permeable Contact Lens

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Trade Name: Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens
Device Generic Name: tisilfocon A rigid gas permeable contact lens
Classification Name: rigid gas permeable contact lens

Predicate Device: Menicon SF-P™ (melafocon A) Rigid Gas Permeable Contact Lens

Device Description:

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens is a lathe-cut nonpolished firm contact lens with spherical front and back surfaces. The posterior curve is selected so as to properly fit an individual eye and the anterior curve selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface

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allows tear exchange between the lens and the cornea. The lens material, tisilfocon A, is a thermoset copolymer derived form fluoro-methacrylate and siloxanylstyrene, bound by cross-linking agents. The lens colors are light blue or clear. The lens is tinted light blue with color additive D & C Green No. 6. A UV absorber 2-(5-Chloro-2H- benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-methylphenol is also added.

Indications for Use:

The Menicon Z™ Rigid Gas Permeable Contact Lens for Daily Wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with nondiseased eyes who are myopic or hyperopic and have an astigmatism of up to 3.00 Diopters (D) that does not interfere with visual acuity. The lens may be disinfected using a chemical disinfection only.

Substantial Equivalence:

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear is substantially equivalent to the Menicon SF-P™ (melafocon A) Rigid Gas Permeable Contact Lens. Both are Hydrophobic Material Group III (fluoro silicone acrylate) and have less than 0.5% water content.

The applicant performed non-clinical and clinical testing on the device in accordance with the FDA Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (May 1994). The non-clinical testing supports the safety and effectiveness of the device from microbiological, toxicological, chemistry, and manufacturing perspectives. The applicant sponsored a randomized, controlled clinical trial in which subjects were randomly assigned in a two-to-one ratio to the Menicon Z™ Rigid Gas Permeable Contact Lens and to the predicate device, the Menicon SF-P™ Rigid Gas Permeable Contact Lens. A total of 118 eyes were enrolled in the 3 month study. Based on the analysis of the detailed data presented in the 510(k), it was determined that the clinical findings for the device, i.e., adverse reactions, positive slit lamp findings, patient symptoms, problems, and complaints, visual acuity, lens replacements, discontinued patients, lens wearing time, and keratometry changes were within expected limits for daily wear contact lens wearers. Visual acuity results

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demonstrated that the Menicon Z™ Rigid Gas Permeable Contact Lens was comparable to the predicate lens.

Conclusion:

Menicon Z™ (tisilfocon A), a Daily Wear Rigid Gas Permeable (nonhydrophobic) contact lens, is a class II medical device. The information submitted in the 510(k) notification established that the device is substantially equivalent to the Menicon SF-P™ Rigid Gas Permeable Contact Lens in that it has the same intended use and comparable technological characteristics as the predicate device and is as safe and effective as that device and does not raise different types of safety and effectiveness questions.

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