

K970019

MAR 25 1997

**VI 510(k) Summary for the
Alternate Designs of Menicon Z™ (tisilfocon A)
Rigid Gas Permeable Contact Lens**

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Summary Prepared December 27, 1996

Trade Name:
Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens
Bifocal design contact lens
Trifocal design contact lens

Device Generic Name:
tisilfocon A (rigid gas permeable contact lens)

Classification Name :
Rigid gas permeable contact lens

Predicate Device:

The spherical design lens of the Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens

Device Description:

The alternate designs of the Menicon Z (tisilfocon A) contact lens are bifocal and trifocal design contact lenses. Conventional bifocal / trifocal designs are employed in the alternate designs of Menicon Z (tisilfocon A) rigid gas permeable contact lenses.

The lens material, tisilfocon A, is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents. The lens is classified fluoro-silicone acrylate, group III, page 16, FDA's premarket notification (510(k)) guidance document for daily wear contact lenses, May 12, 1994. The lens is tinted light blue with color additive D&C Green No. 6 (21 CFR 74.3206). Also, UV absorber (2-(5-Chloro-2H-benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-methylphenol) is added.

Indications for Use:

The alternate designs of the Menicon Z (tisilfocon A) contact lens are indicated for **daily wear** for the correction of visual acuity in not-aphakic persons with non-diseased presbyopic eyes that are myopic or hyperopic and which may exhibit astigmatism of 3.00 Diopters (D) or less that does not interfere with visual acuity. The lens may be disinfected using a chemical disinfection only.

Substantial Equivalence:

The alternate designs of the Menicon Z (tisilfocon A) contact lens are substantially equivalent to the spherical design of the Menicon Z (tisilfocon A) contact lens, which is a lens with an existing USAN

The applicant performed non-clinical and clinical testing on the spherical design of the Menicon Z (tisilfocon A) contact lens 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 spherical design of the Menicon Z™ Rigid Gas Permeable Contact Lens and to that of the Menicon SF-P™ Rigid Gas Permeable Contact Lens.

It was determined that the clinical findings 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 the expected limits for daily wear lens wearers.

Conclusion:

The alternate designs of the Menicon Z (tisilfocon A) contact lens are a class II medical device. The information submitted in the 510(k) notification established the device is substantially equivalent to the spherical design of the Menicon Z (tisilfocon A) contact lens in that the device has the comparable characteristics as the predicate device and is as safe and effective as the predicate device and does not raise different types of safety and effective questions.