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Summary of 510(k) Submission K962804

1. Name and address of submitter

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2. Identification of Device

a. Trade name: ACUVUE (etafilcon A) Contact Lens clear and visibility tint with UV blocker
b. Common or Usual Name: Soft (hydrophilic Contact Lens (daily wear)
c: Classification II

3. Predicate Device

ACUVUE (etafilcon A) Contact Lens clear and with visibility tint

4. Description of Device

The ACUVUE (etafilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens, spherical multifocal lens and an astigmatic (toric) lens. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1,1,1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The ACUVUE Contact Lens with visibility tint is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5 % in the UVB range of 280 to 315 nm and less than 30 % in the UVA range of 316 to 380 nm.

5. Intended Use (indications)

The ACUVUE Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00 D of astigmatism or less.

The ACUVUE MULTIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The ACUVUE Toric Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

Eye care practitioners may prescribe the lens for either single-use disposable wear or for frequent/ planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system only.

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6. a. Characteristics

A characteristics comparison to the predicate device is presented below.

Characteristic	Predicate Device Measured (avg)	Subject Device Measured (avg)	Subject and Predicate Device Label Claim
% Water Content	59%	60%	58%
Refractive Index @ 20° C	1.40	1.40	1.40 $\pm$ 0.01
Dk (Fatt method, non-edge corrected)	30 x 10^{-11} (cm^2/sec)* (ml O_2/ml*mmHg)	26 x 10^{-11} (cm^2/sec)* (ml O_2/ml*mmHg)	28 $\pm$ 5.6 x 10^{-11} cm^2/sec)* (ml O_2/ml*mmHg)
Color	light blue	light blue	light blue
% T @ 593 nm	Conforms	Conforms	85 % minimum
% T @ 280 - 315 nm	N/A	2.0	avg < 5%
% T @ 316 - 380 nm	N/A	15.3	avg < 30%
Base Curve Radius, mm	8.84 mm	8.87 mm	8.8 mm
Diameter, mm	14.02 mm	14.05 mm	14.0 mm
Power, Diopters	-0.95 D	-0.97 D	-1.00 D

6.b. Nonclinical studies

The following information summarizes the nonclinical data. The references to studies with lens care apply only to the frequent replacement wear schedule of the device.

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6. b. 1. Toxicology

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the molded etafilcon A soft (hydrophilic) contact lenses with visibility and UV absorber. The Ocular Irritation and USP Systemic Toxicity studies indicate the extracts would not be considered ocular irritants, nor systemically toxic under the conditions of the study. The Cytotoxicity study indicates that the lens is not cytotoxic under the conditions of the study. No additional toxicology studies have been conducted on the plastic primary packaging materials, as the materials are the same as those previously tested and reported under N18-033.

Two additional toxicology studies have been conducted on the neat UV absorbing additive. These studies were: (1) 4 week Oral Gavage Toxicity Study in Rats with a 2 week Recovery and (2) The Ames Salmonella/Microsome Reverse Mutation Assay - Preincubation Method. The results of the studies were: Based on the data presented in the 4 Week Oral Gavage Toxicity Study, the no observable adverse effect level for the test article in rats appears to be 50 mg/kg; the results of Ames Salmonella/Microsome Reverse Mutation Assays - Preincubation Method indicate that under the conditions of the study, the test article did not induce positive increases in the numbers of histidine revertants per plate of any of the tester strains either in the presence or absence of Aroclor-induced rat liver microsomes.

6.b.2. Microbiology

The lens sterilization process, moist heat sterilization, has been validated to deliver a minimum SAL of 10^{-6}. The lens falls into FDA Group IV. The lens care product manufacturers have established a reasonable assurance of disinfection efficacy of their care products with the lens groups for which they are approved. The lens will be presented in the same primary package currently used for other products approved under N18-033. There is shelf-life stability data supporting that the lens remains sterile through the shelf-life claimed for the product.

6.b.3. Chemistry

Material property data were generated on the current and modified materials. There are no significant differences in the properties of the current or modified materials except where expected, % T in the UV range. The lens care product manufacturers have previously shown compatibility of group IV lenses with their products.

6.b.4. Shelf-life

Shelf-life stability protocols have been approved under N18-033. The initial shelf-life of the lens will be declared based on the data generated under an approved protocol. Shelf-life will not be claimed until a minimum of six months of real time data have been collected and found to be acceptable.

6.b.5. Leachables

Studies were conducted to determine the leachable materials from the finished lens. The results indicate that, at the levels of detection reported, there are no leachable monomers or additives.

6.c. Summary of Clinical Studies

Clinical studies were not required for this Premarket notification as the USAN name and process are the same as the predicate device.

6.d. Conclusions Drawn from Studies

1. Validity of Scientific Data

Toxicology studies were conducted by a contract laboratory under Good Laboratory Practice Regulations. The laboratory has been audited by Vistakon and found to be in compliance. Microbiology, chemistry, shelf-life stability, and leachables studies were conducted by in-house laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

2. Safety and Effectiveness

The data presented in this Premarket Notification support the safety and effectiveness of the subject device when used in accordance with the labeled directions for use and for the requested indication. The subject device has been shown to be substantially equivalent to the predicate device.

3. Risk and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on an daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.