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## 510(k) SUMMARY *K 964696*

Trade Name Sunsoft (methafilcon A) Soft (Hydrophilic)  
DW Contact Lens

Generic Name: Soft Contact Lens

Equivalent Device: Sunsoft (methafilcon A) Soft (Hydrophilic)  
Contact Lens

### Description and Intended Use:

The Sunsoft (methafilcon A) Soft (Hydrophilic) Contact Lens is a random copolymer of 2-hydroxyethylmethacrylate and methacrylic acid. When hydrated, the lens consists of 45% methafilcon A and 55% water by weight when immersed in normal saline. It is indicated for the correction of visual acuity.

### Assessment Of Equivalence:

#### Biocompatibility

Cytotoxicity, acute systemic toxicity and ocular irritation studies were conducted with samples of tinted lenses produced with the proposed static molding and lathing process. Test results showed no evidence of cellular or systemic toxicity, or ocular irritation.

#### Physical/Optical Characteristics

Light transmittance, refractive index, linear expansion, oxygen permeability and tensile strength were determined in samples of tinted lenses produced by static and centrifugal molding. Lenses were of similar thickness and power. A comparison of the data from this study showed that the lenses were equivalent in physical and optical characteristics.

#### Manufacturing Process Validation

Two replicate production batches of three lens designs, that is, toric, asphere and sphere, were produced using the proposed production method. Thirty samples per batch were evaluated for axis and cylinder power (toric) base curve (sphere and

asphere), diameter, lens thickness and dioptric power. All measurements were within specification. Evaluation of process capability for dioptric power resulted in  $C_{pk}$  values of 1.2 or greater for all batches.

### Conclusions

Biocompatibility studies of tinted lenses produced with the proposed manufacturing process showed no evidence of cellular or systemic toxicity, or ocular irritation. A comparative evaluation of this lens with lenses manufactured using the approved centrifugally molded/back lathed process showed that the two methods of production result in lenses that are equivalent in physical and optical characteristics. The static molding process is highly capable, as evidenced by a process validation study in which the manufacture of sphere, asphere and toric lens designs met all specifications of lenses manufactured by currently approved molding technology.



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