FDA approves first contact lens that slows myopia progression

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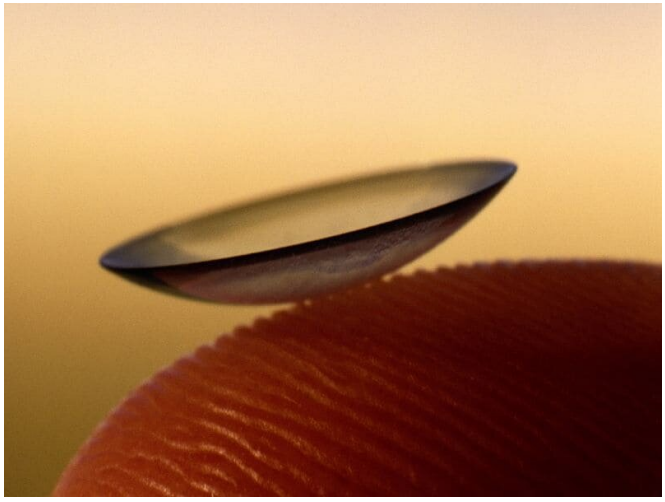

(HealthDay)—MiSight, the first contact lens indicated to slow the progression of myopia in children ages 8 to 12 years, has been approved by the U.S. Food and Drug Administration, the agency announced Friday.

The single-use, disposable, soft contact lenses should be discarded after one-day use and are not intended to be worn overnight. They are indicated to correct and slow progression of myopia in children with healthy eyes, the FDA noted. Like a standard corrective lens, one part of the MiSight contact lens corrects the refractive error to improve distance vision. Concentric peripheral rings in the lens also focus part of the light in front of the retina to reduce the stimulus causing myopia progression.

The FDA approved MiSight based on data from a prospective clinical trial at four clinical sites and real-world evidence. Safety and effectiveness of MiSight were demonstrated in a three-year randomized, controlled clinical trial of 135 children ages 8 to 12 years old at the start of treatment with MiSight or a conventional soft contact lens. During the entire three years, children who wore MiSight lenses had less progression of myopia compared with those who wore conventional soft contact lenses. Researchers also found that children who wore MiSight lenses had less change in the axial length of the eyeball at each yearly checkup. No serious ocular adverse events were reported for any patients.

The FDA also reviewed real-world data from a retrospective analysis of medical records of 728 children aged 8 to 12 years old from seven community eye care clinics. Data showed a similar rate of corneal ulcer cases in children who wore MiSight as in adults who wear contact lenses daily.

Approval was granted to CooperVision.

More information: More Information