FDA NEWS RELEASE

FDA approves first contact lens indicated to slow the progression of nearsightedness in children

For Immediate Release:

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The U.S. Food and Drug Administration today approved the first contact lens indicated to slow the progression of myopia (nearsightedness) in children between the ages of 8 and 12 years old at the initiation of treatment. The MiSight contact lens is a single use, disposable, soft contact lens that is discarded at the end of each day, and is not intended to be worn overnight.

“Today’s approval is the first FDA-approved product to slow the progression of myopia in children, which ultimately could mean a reduced risk of developing other eye problems,” said Malvina Eydelman, M.D., director of the Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices in the FDA’s Center for Devices and Radiological Health.

Myopia is the most frequent cause of correctable visual impairment worldwide. Myopia occurs when the eye grows too long from front to back (axial length). Instead of focusing images on the retina, images are focused at a point in front of the retina. As a result, people with myopia have good near vision, but poor distance vision that can be corrected with glasses or contact lenses.

Myopia is common in children and tends to increase as they get older. If a person develops severe myopia as a child, they may be susceptible to other eye problems such as early cataracts or a detached retina during adulthood. The MiSight soft contact lenses are meant to be worn daily to correct nearsightedness and slow the progression of myopia in children with healthy eyes. When placed on the eye, one part of the MiSight contact lens corrects the refractive error to improve distance vision in nearsighted eyes, similar to a standard corrective lens. In addition, concentric peripheral rings in the lens focus part of the light in front of the retina (the back of the eye). This is believed to reduce the stimulus causing the progression of myopia.

The approval of MiSight was based on data obtained from a prospective clinical trial at four clinical sites and real-world evidence. The safety and effectiveness of MiSight was studied in a three-year randomized, controlled clinical trial of 135 children ages 8 to 12 at the start of treatment who used MiSight or a conventional soft contact lens. The trial showed that for the full three-year period, the progression in myopia of those wearing MiSight lenses was less than those wearing conventional soft contact lenses. In addition, subjects who used MiSight had less change in the axial length of the eyeball at each annual checkup. Over the course of the trial, there were no serious ocular adverse events in either arm of the study.

Additionally, to estimate the rate of vision-threatening corneal infections (i.e., corneal ulcers) among children and adolescents who wear soft contact lenses daily, the FDA reviewed real world data from a retrospective analysis of medical records of 782 children ages 8 to 12 years old from seven community eye care clinics. The results showed a rate comparable to the rate of ulcer cases among adults who wear contact lenses daily.

As part of the approval of MiSight, the sponsor is required to conduct a postmarket study of the contact lenses to further evaluate the safety and effectiveness of the product as indicated.

The FDA granted approval of MiSight to CooperVision Inc. The device was approved using the Premarket Approval (PMA) pathway (/medical-devices/premarket-submissions/premarket-approval-pma). Premarket approval is the most stringent type of device marketing application required by FDA and is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use(s).

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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