

EssilorLuxottica's Stellest® spectacle lens - The first and only U.S. Food and Drug Administration (FDA) market authorized spectacle lens clinically proven to slow myopia progression in children

September 25, 2025 – EssilorLuxottica a global leader in the eyecare and eyewear industry announced the U.S. Food and Drug Administration (FDA) has granted market authorization for its Essilor Stellest lens. This FDA authorization follows the lens's earlier designation as a Breakthrough Device in 2021, underscoring its transformative potential in addressing the global myopia epidemic.

With childhood myopia on the rise—projected to affect 740 million children globally by 2050, the development and clinical validation of the Essilor Stellest® lens contributes directly to improving long-term eye health outcomes for future generations.



The effectiveness of the Essilor Stellest lens is evidenced by clinical data from the FIN-3101 randomized, controlled clinical trial, conducted at nine clinical sites in the USA, including the SUNY College of Optometry's, Clinical Vision Research Center (CVRC). Adjunct Assistant Professor Josianne Manasse, OD, was Principal Investigator of the clinical trial for the CVRC, overseeing all aspects of the study for participants between the ages of 6 and 12 years.

Based on robust clinical data showing an average 71% reduction in myopia progression over two years, the Essilor Stellest lens provides eyecare professionals with an evidence-backed, reliable solution for helping families address the challenges of myopia, improving both short-term and long-term eye health outcomes.

This new lens technology evolves the traditional corrective lenses into a true medical treatment, and it marks the beginning of a new era for eyecare professionals in addressing myopia.

The Essilor Stellest® spectacle lens is a class 2 product according to FDA regulation. Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner. It is currently available to eyecare professionals across the U.S., following its successful international rollout.

***EssilorLuxottica's
commitment to
innovation and
public health is
exemplified
through this
achievement, and
contributions from
the CVRC and other
clinical sites have
helped redefine the
role of spectacle
lenses from
corrective tools to
medical treatments***

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