

**K864594 DUALENZ LOW VISION EYEWEAR**Jan 20, 1987  
60 days to decisionK864594 · Product code: **HKK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k864594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Telescope, Spectacle, Low-vision (HKK)
Date received	Nov 21, 1986
Decision date	Jan 20, 1987
Days to decision	60 days
Third-party review	No

**APPLICANT**

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Company	<b>Global Eye Care, Inc.</b>
Location	Rochester, NY, US
Contact	JAMES C BRADFORD
510(k) history	1 submissions · 1 cleared · 1987-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864594/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026