

K800521 THE LENS OR OMMI-GARDMar 12, 1980
6 days to decisionK800521 · Product code: **HQG** · Ophthalmic
Source: <https://www.510kdatabase.net/k800521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Spectacle, Non-custom (prescription) (HQG)
Date received	Mar 6, 1980
Decision date	Mar 12, 1980
Days to decision	6 days
Third-party review	No

APPLICANT

Company	Gentex Corporation
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1977-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k800521/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026