FDA 510(k) Premarket Notification

K800521 THE LENS OR OMMI-GARD

CLEARED

Mar 12, 1980
6 days to decision

K800521 · 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