FDA 510(k) Premarket Notification

K800192 DURALITE LENS

CLEARED

Mar 12, 1980
43 days to decision

K800192 · Product code: **HPX** · Ophthalmic
Source: https://www.510kdatabase.net/k800192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (polymethylmethacrylate) (HPX)
Date received	Jan 29, 1980
Decision date	Mar 12, 1980
Days to decision	43 days
Third-party review	No

APPLICANT

Company	**American Optical Corp.**
Location	Mchenry, IL, US
510(k) history	35 submissions · 35 cleared · 1976-1995