FDA 510(k) Premarket Notification

K791523 VISALENS ALL PURPOSE SOLUTION FOR LENS

CLEARED

Feb 19, 1980
193 days to decision

K791523 · Product code: **HPX** · Ophthalmic
Source: https://www.510kdatabase.net/k791523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (polymethylmethacrylate) (HPX)
Date received	Aug 10, 1979
Decision date	Feb 19, 1980
Days to decision	193 days
Third-party review	No

APPLICANT

Company	**Pfizer, Inc.**
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1977-2018

Pfizer, Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered in Manhattan, New York City. Founded in 1849, Pfizer is one of the oldest pharmaceutical companies in North America. Pfizer's FDA 510(k) regulatory record includes cleared devices from total submissions, spanning 1977 to 2018. The company's device portfolio demonstrates strength in orthopedic devices, including surgical implants and fixation systems. This regulatory activity is now historical, with no clearances recorded in the past five years. The company's cleared device...