FDA 510(k) Premarket Notification

K915630 OPHTIMPLANT

CLEARED

Mar 2, 1992
76 days to decision

K915630 · Product code: **HPZ** · Ophthalmic
Source: https://www.510kdatabase.net/k915630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Dec 17, 1991
Decision date	Mar 2, 1992
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oculo Plastik, Inc.**
Location	Montreal, Quebec Canada, CA
Contact	DURETTE
510(k) history	13 submissions · 13 cleared · 1990-2013