

K934834 EPTFE SHEET COVERING FOR OCULAR IMPLANTMay 5, 1994
209 days to decisionK934834 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k934834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Oct 8, 1993
Decision date	May 5, 1994
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934834/> 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 9, 2026