

K890081 CALIUS-ISABEL CANOVAS SUNGLASSESMar 9, 1989
58 days to decisionK890081 · Product code: **HQY** · Ophthalmic
Source: <https://www.510kdatabase.net/k890081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sunglasses (non-prescription Including Photosensitive) (HQY)
Date received	Jan 10, 1989
Decision date	Mar 9, 1989
Days to decision	58 days
Third-party review	No

APPLICANT

Company	Roseburg SA
Location	Washington, DC, US
Contact	DARIENNE MOYER
510(k) history	24 submissions · 23 cleared · 1985-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890081/>, 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 May 22, 2026