

K980647 EYE IRRIGATOR MODEL #2020May 15, 1998
87 days to decisionK980647 · Product code: **KYG** · Ophthalmic
Source: <https://www.510kdatabase.net/k980647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Irrigation, Ocular Surgery (KYG)
Date received	Feb 17, 1998
Decision date	May 15, 1998
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eye-Deal Ocular Safety Products, Inc.
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980647/> 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 29, 2026