

K912891 HEIDELBERG RETINA TOMOGRAPHSep 27, 1991
88 days to decisionK912891 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k912891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Jul 1, 1991
Decision date	Sep 27, 1991
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heidelberg Engineering
Location	Carlsbad, CA, US
Contact	GERHARD ZINSER
510(k) history	9 submissions · 9 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912891/> 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 20, 2026