

K081858 RETCAM 3 OPHTHALMIC IMAGING SYSTEMNov 5, 2008
127 days to decisionK081858 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k081858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 1, 2008
Decision date	Nov 5, 2008
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clarity Medical Systems
Location	Pleasanton, CA, US
Contact	GARY A SEEGER
510(k) history	4 submissions · 4 cleared · 2008-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081858/> 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 19, 2026