

**K994340 CLINICAL SPECULAR MICROSCOPE, MODEL HAI
CL-1000XYZ**Sep 20, 2000
272 days to decisionK994340 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k994340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Dec 23, 1999
Decision date	Sep 20, 2000
Days to decision	272 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hai Laboratories, Inc.
Location	Sound Beach, NY, US
Contact	RICHARD C LANZILLOTTO
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994340/>. 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