

K950797 HALOGEN OPHTHALMO-OTOSCOPE SET BX A - 134Mar 28, 1995
35 days to decisionK950797 · Product code: **HLJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k950797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Battery-powered (HLJ)
Date received	Feb 21, 1995
Decision date	Mar 28, 1995
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Neitz Instruments Company, Ltd.
Location	Washington, DC, US
Contact	YASUO KAWANO
510(k) history	24 submissions · 24 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950797/> 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