

K093495 OTOSCOPE AND OPHTHALMOSCOPE DIAGNOSTIC INSTRUMENT KITSNov 19, 2010
374 days to decisionK093495 · Product code: **HLJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k093495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Battery-powered (HLJ)
Date received	Nov 10, 2009
Decision date	Nov 19, 2010
Days to decision	374 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Diagnostic Corp.
Location	Mchenry, IL, US
Contact	MICHAEL FALCO
510(k) history	39 submissions · 39 cleared · 1980-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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