

K951728 SCHEPENS-YOSHIDA VIDEO BINOCULAR INDIRECT OPTHALMSCOPE

Mar 19, 1997
706 days to decision

K951728 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k951728/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Apr 13, 1995
Decision date	Mar 19, 1997
Days to decision	706 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mira, Inc.
Location	Waltham, MA, US
Contact	ROGER R O' BRIEN
510(k) history	21 submissions · 21 cleared · 1984-1997

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 Device record: <https://www.510kdatabase.net/k951728/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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