FDA 510(k) Premarket Notification

# K951338 INDIRECT OPHTHALMOSCOPE VIDEO SYSTEM IO0 A TV

**CLEARED**

Apr 7, 1995
14 days to decision

K951338 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k951338/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ophthalmoscope, Ac-powered (HLI) |
| Date received | Mar 24, 1995 |
| Decision date | Apr 7, 1995 |
| Days to decision | 14 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 |