

**K972440 CATARACTSCREENER CT - S**Sep 30, 1997  
92 days to decisionK972440 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k972440/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Camera, Ophthalmic, Ac-powered (HKI) |
| Date received         | Jun 30, 1997                         |
| Decision date         | Sep 30, 1997                         |
| Days to decision      | 92 days                              |
| Third-party review    | No                                   |
| Summary / Statement   | Statement                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Neitz Instruments Company, Ltd.</b>  |
| Location       | Washington, DC, US                      |
| Contact        | MASAO SUGASAWA                          |
| 510(k) history | 24 submissions · 24 cleared · 1994-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972440/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026