

K982689 WINSTATION RETINAL IMAGEROct 23, 1998
81 days to decisionK982689 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k982689/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Camera, Ophthalmic, Ac-powered (HKI) |
| Date received | Aug 3, 1998 |
| Decision date | Oct 23, 1998 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ophthalmic Imaging Systems |
| Location | Sacramento, CA, US |
| Contact | BETH A SOPER |
| 510(k) history | 5 submissions · 5 cleared · 1991-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982689/> 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 19, 2026