

**K000368 EYECAP IMAGING SYSTEM**May 4, 2000  
90 days to decisionK000368 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k000368/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Camera, Ophthalmic, Ac-powered (HKI) |
| Date received         | Feb 4, 2000                          |
| Decision date         | May 4, 2000                          |
| Days to decision      | 90 days                              |
| Third-party review    | No                                   |
| Summary / Statement   | Statement                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Clement Clarke Intl., Ltd.</b>     |
| Location       | Harlow, GB                            |
| Contact        | M.J. WILKINSON                        |
| 510(k) history | 6 submissions · 6 cleared · 1997-2006 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000368/> 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 May 25, 2026