

**K872111 ORTHOTONE**Nov 16, 1988  
534 days to decisionK872111 · Product code: **HLL** · Ophthalmic  
Source: <https://www.510kdatabase.net/k872111/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Monitor, Eye Movement (HLL)        |
| Date received         | Jun 1, 1987                        |
| Decision date         | Nov 16, 1988                       |
| Days to decision      | 534 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Orthotone Corp.</b>                |
| Location       | New York, NY, US                      |
| Contact        | JOHN ORZUCHOWSKI                      |
| 510(k) history | 1 submissions · 1 cleared · 1988-1988 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k872111/>, 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 30, 2026