

**K964312 MENTOR TONO-PEN 3**Nov 26, 1996  
28 days to decisionK964312 · Product code: **HKY** · Ophthalmic  
Source: <https://www.510kdatabase.net/k964312/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Tonometer, Manual (HKY)            |
| Date received         | Oct 29, 1996                       |
| Decision date         | Nov 26, 1996                       |
| Days to decision      | 28 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mentor Ophthalmics, Inc.</b>       |
| Location       | Norwell, MA, US                       |
| Contact        | DAVID M DOWNEY                        |
| 510(k) history | 4 submissions · 4 cleared · 1996-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964312/> 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 20, 2026