

**K053475 OPTIPOINT CORNEAL MARKER, MODEL VPT-OPT-450**Mar 3, 2006  
79 days to decisionK053475 · Product code: **HMR** · Ophthalmic  
Source: <https://www.510kdatabase.net/k053475/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Marker, Ocular (HMR)               |
| Date received         | Dec 14, 2005                       |
| Decision date         | Mar 3, 2006                        |
| Days to decision      | 79 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Refractec, Inc.</b>                |
| Location       | Irvine, CA, US                        |
| Contact        | GARY MOCNIK                           |
| 510(k) history | 2 submissions · 1 cleared · 1998-2006 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053475/> 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 28, 2026