

**K964891 ORBSHOT KERATOMETER**Mar 26, 1997  
110 days to decisionK964891 · Product code: **MMQ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k964891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Topographer, Corneal, Ac-powered (MMQ)
Date received	Dec 6, 1996
Decision date	Mar 26, 1997
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orbtek, Inc.</b>
Location	Salt Lake City, UT, US
Contact	PIER CALACINO
510(k) history	2 submissions · 2 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964891/> 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 29, 2026