

**K110986 OPTOMED SMARTSCOPE M5 EY3 AND M5 ES1**May 16, 2011  
38 days to decisionK110986 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k110986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 8, 2011
Decision date	May 16, 2011
Days to decision	38 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optomed OY</b>
Location	Oulu, FI
Contact	LAURA PIILA
510(k) history	5 submissions · 5 cleared · 2009-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110986/> 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 30, 2026