

**K201325 Optomed Smartscope M5 with Optomed Smartscope  
FA**Nov 20, 2020  
186 days to decisionK201325 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k201325/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	May 18, 2020
Decision date	Nov 20, 2020
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optomed Oyj</b>
Location	Oulu, FI
Contact	Jyri Leskelä
510(k) history	1 submissions · 1 cleared · 2020-2020

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201325/> 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