

K132186 OPTOMED SMARTSCOPE M5 / OPTOMED SMARTSCOPE EY4 / OPTOMED SMARTSCOPE ES2

Dec 18, 2013
156 days to decision

K132186 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k132186/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 15, 2013
Decision date	Dec 18, 2013
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optomed OY
Location	Oulu, FI
Contact	JYRI LESKELA, QUALITY MANAGER
510(k) history	5 submissions · 5 cleared · 2009-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132186/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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