

K180378 Optomed Aurora Camera with Aurora Retinal Module and Aurora Anterior ModuleApr 5, 2018
52 days to decisionK180378 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k180378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Feb 12, 2018
Decision date	Apr 5, 2018
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optomed OY
Location	Oulu, FI
Contact	Jyri Leskela
510(k) history	5 submissions · 5 cleared · 2009-2018

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