

K163021 HAAG-STREIT FUNDUS MODULE 300Apr 11, 2017
162 days to decisionK163021 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k163021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 31, 2016
Decision date	Apr 11, 2017
Days to decision	162 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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