

K221111 Non-Mydriatic Retinal Camera NW500Aug 29, 2022
136 days to decisionK221111 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k221111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 15, 2022
Decision date	Aug 29, 2022
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topcon Corporation
Location	North Reading, MA, US
Contact	Ryota Kitawaki
Website	http://www.topcon.com
510(k) history	13 submissions · 13 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	Oconnell Regulatory Consultants, Inc.
Contact	Maureen OConnell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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