FDA 510(k) Premarket Notification

K221111 Non-Mydriatic Retinal Camera NW500

CLEARED

Aug 29, 2022
136 days to decision

K221111 · 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