

K210197 NFC-600 Automated Portable Retinal CameraApr 13, 2021
78 days to decisionK210197 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k210197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jan 25, 2021
Decision date	Apr 13, 2021
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Crystalvue Medical Corporation
Location	Taoyuan City, TW
Contact	Oliver Lin
510(k) history	3 submissions · 3 cleared · 2018-2021

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