

K182199 NFC-700 non-mydriatric auto fundus cameraJan 2, 2019
141 days to decisionK182199 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k182199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Aug 14, 2018
Decision date	Jan 2, 2019
Days to decision	141 days
Third-party review	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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