FDA 510(k) Premarket Notification

K202221 VX650

CLEARED

Jan 29, 2021
176 days to decision

K202221 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k202221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Aug 6, 2020
Decision date	Jan 29, 2021
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Luneau Technology Operations**
Location	Pont-De-L'Arche, FR
Contact	Yossi Constantinis
510(k) history	1 submissions · 1 cleared · 2021-2021