FDA 510(k) Premarket Notification

CLEARED

K200254 Mydriatic Hyperspectral Retinal Camera (MHRC-C1)

Apr 27, 2020
84 days to decision

K200254 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k200254/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Feb 3, 2020
Decision date	Apr 27, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Optina Diagnostics**
Location	Montreal, CA
Contact	Jean-Philippe Sylvestre
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	Elisa Harvey

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200254/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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