FDA 510(k) Premarket Notification

K973950 RETINAL CUBE

K973950 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k973950/

CLEARED

Dec 12, 1997
57 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 16, 1997
Decision date	Dec 12, 1997
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Applied Spectral Imaging , Ltd.**
Location	Ra'Ananna 43373, IL
Contact	MICHAEL ADEL
510(k) history	7 submissions · 7 cleared · 1997-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k973950/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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