FDA 510(k) Premarket Notification

K080180 MODIFICATION TO RETINAL FUNCTION IMAGER (RFI)

CLEARED

Jun 11, 2008
139 days to decision

K080180 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k080180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jan 24, 2008
Decision date	Jun 11, 2008
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Optical Imaging , Ltd.**
Location	Washington, Dc, DC, US
Contact	JONATHAN S KAHAN
510(k) history	2 submissions · 2 cleared · 2006-2008