FDA 510(k) Premarket Notification

K123208 DIGITAL RETINAL CAMERA

CLEARED

Mar 19, 2013
158 days to decision

K123208 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k123208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 12, 2012
Decision date	Mar 19, 2013
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Canon Inc. -Medical Equipment Group**
Location	Tachikawa-Shi, Tokyo, JP
Contact	IZUMI MARUO
510(k) history	11 submissions · 11 cleared · 2010-2018