

**K123208 DIGITAL RETINAL CAMERA**Mar 19, 2013  
158 days to decisionK123208 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k123208/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123208/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026