

**K080883 CR-1**Apr 24, 2008  
24 days to decisionK080883 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k080883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Mar 31, 2008
Decision date	Apr 24, 2008
Days to decision	24 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canon, Inc.</b>
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	SHEILA DRISCOLL
Website	<a href="http://www.canon.it/">http://www.canon.it/</a>
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in Aomae, Tokyo, specializing in optical, imaging, and industrial products including lenses, cameras, scanners, and semiconductor manufacturing equipment. Canon has received FDA 510(k) clearances from total submissions since 1994. The company's regulatory focus centers on Radiology devices, which represent 74% of submissions. The latest clearance was in 2024, demonstrating continued active engagement with FDA regulatory pathways. Canon's cleared device portfolio includes digital radiography systems and ophth...

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