

K090466 DIGITAL RETINAL CAMERA, CR-1 MARK IIMar 23, 2009
30 days to decisionK090466 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k090466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Feb 21, 2009
Decision date	Mar 23, 2009
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Canon, Inc.
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	SHEILA DRISCOLL
Website	http://www.canon.it/
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...
