

**K940516 AUTO REFF-30**Jul 12, 1994  
158 days to decisionK940516 · Product code: **HKO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k940516/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Refractometer, Ophthalmic (HKO)
Date received	Feb 4, 1994
Decision date	Jul 12, 1994
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canon, Inc.</b>
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	H. UCHII
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 Aomori, 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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