

**K041546 DIGITAL FUNDUS CAMERA, MODEL CF-60DSI**Jun 23, 2004  
14 days to decisionK041546 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k041546/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jun 9, 2004
Decision date	Jun 23, 2004
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

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...

---