

K201273 ImageSPECTRUMSep 25, 2020
136 days to decisionK201273 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k201273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	May 12, 2020
Decision date	Sep 25, 2020
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Canon, Inc.
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	Akira Hirai
Website	http://www.canon.it/
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in Ōhta, 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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Device record: <https://www.510kdatabase.net/k201273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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