FDA 510(k) Premarket Notification

K182942 Canon OCT-A1

CLEARED

Jul 24, 2019
274 days to decision

K182942 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k182942/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Oct 23, 2018
Decision date	Jul 24, 2019
Days to decision	274 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	Tatsuya Yamazaki
Website	http://www.canon.it/
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in ÅŒta, 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...

REGULATORY CONSULTANT

Consulting firm	**Ora, Inc.**
Contact	Ryan Bouchard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03716492

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - *No results published to ClinicalTrials.gov*
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03716492