FDA 510(k) Premarket Notification

CLEARED

K201122 Canon non-mydriatic retinal camera CR series

Jul 23, 2020
87 days to decision

K201122 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k201122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 27, 2020
Decision date	Jul 23, 2020
Days to decision	87 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 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...