FDA 510(k) Premarket Notification

CLEARED

K220098 Digital Radiography CXDI-Pro, Digital Radiography D1

Feb 4, 2022
23 days to decision

K220098 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k220098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 12, 2022
Decision date	Feb 4, 2022
Days to decision	23 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...

REGULATORY CONSULTANT

Consulting firm	**Ken Block Consulting**
Contact	Gregory Woodard

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

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Device record: https://www.510kdatabase.net/k220098/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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