FDA 510(k) Premarket Notification

K212553 DIGITAL RADIOGRAPHY CXDI-Pro, D1

CLEARED

Sep 9, 2021
27 days to decision

K212553 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k212553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Aug 13, 2021
Decision date	Sep 9, 2021
Days to decision	27 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