FDA 510(k) Premarket Notification

CLEARED

K131106 DIGITAL RADIOGRAPHY CXDI-701C WIRELESS, DIGITAL RADIOGRAPHY CXDI-70IG WIRELESS, DIGITAL RADIOGRAPHY CXDI-801C WIRELESS,

Jul 3, 2013
75 days to decision

K131106 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k131106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Apr 19, 2013
Decision date	Jul 3, 2013
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Canon, Inc.**
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	DIANE RUTHERFORD
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...