FDA 510(k) Premarket Notification

K062221 CXDI-40EC

CLEARED

Aug 17, 2006
15 days to decision

K062221 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k062221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Aug 2, 2006
Decision date	Aug 17, 2006
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Canon, Inc.**
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	SHEILA DRISCOLL
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...