

**K203849 General Radiography CXDI-CS01**Jan 26, 2021  
26 days to decisionK203849 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k203849/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Dec 31, 2020
Decision date	Jan 26, 2021
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canon, Inc.</b>
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	Akira Hirai
Website	<a href="http://www.canon.it/">http://www.canon.it/</a>
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in Ōhta, 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**

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Consulting firm	<b>Ken Block Consulting</b>
Contact	Gregory Woodard

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k203849/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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