

K252503 Intelligent NRApr 30, 2026
265 days to decisionK252503 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k252503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 8, 2025
Decision date	Apr 30, 2026
Days to decision	265 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	Masahiro Abe
Website	http://www.canon.it/
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in AECeta, 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, LLC
Contact	Saori Sawaki

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k252503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026