

K200887 AS-10Apr 15, 2020
13 days to decisionK200887 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k200887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Apr 2, 2020
Decision date	Apr 15, 2020
Days to decision	13 days
Third-party review	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 Aomori, 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 ophthalm...
