

K233107 Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5Aug 30, 2024
338 days to decisionK233107 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k233107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 27, 2023
Decision date	Aug 30, 2024
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Canon Medical Systems Corporation
Location	Otawara-Shi, JP
Contact	Paul Biggins
Website	https://global.medical.canon
510(k) history	96 submissions · 96 cleared · 2018-2026

Canon Medical Systems Corporation is a Japanese medical equipment manufacturer based in Ōtawara, Tochigi. Now part of Canon Inc. following its 2016 acquisition, the company continues to operate as a leading provider of diagnostic imaging systems. Canon Medical Systems has received FDA 510(k) clearances from total submissions since 2018. The company specializes exclusively in Radiology devices, with its latest clearance in 2026, demonstrating continued regulatory activity and product innovation. The company's product portfolio centers on advanced imaging technologies incl...

REGULATORY CONSULTANT

Consulting firm	Canon Medical Systems, USA
Contact	Orlando Tadeo Jr.

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