FDA 510(k) Premarket Notification

CLEARED

K251602 Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with aEvolve Imaging

Oct 10, 2025
136 days to decision

K251602 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k251602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	May 27, 2025
Decision date	Oct 10, 2025
Days to decision	136 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	Orlando Tadeo
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 ÅŒtawara, 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	Jonathan Toy

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