

**K253584 Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with aEvolve Imaging (FOV Extension)**Mar 10, 2026  
113 days to decisionK253584 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k253584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 17, 2025
Decision date	Mar 10, 2026
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canon Medical Systems Corporation</b>
Location	Otawara-Shi, JP
Contact	Orlando Tadeo, Jr.
Website	<a href="https://global.medical.canon">https://global.medical.canon</a>
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**

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Consulting firm	<b>Canon Medical Systems, USA</b>
Contact	Jonathan Toy

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/k253584/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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