

**K182546 Alphenix, INFX-8000H/B, V8.0**Oct 17, 2018  
30 days to decisionK182546 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k182546/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 17, 2018
Decision date	Oct 17, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canon Medical Systems Corporation</b>
Location	Otawara-Shi, JP
Contact	Paul Biggins
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...

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