

K203551 Alphenix, INFX-8000V/B, /S, V9.1Dec 18, 2020
14 days to decisionK203551 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k203551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 4, 2020
Decision date	Dec 18, 2020
Days to decision	14 days
Third-party review	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...
