

**K251645 Self-Propelled CT Scan Base Kit, CGBA-035A**Sep 26, 2025  
120 days to decisionK251645 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k251645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 29, 2025
Decision date	Sep 26, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP

**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/k251645/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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