

**K253596 Aquilion ONE (TSX-308A/TSX-306A) V2.0**May 20, 2026  
183 days to decisionK253596 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k253596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 18, 2025
Decision date	May 20, 2026
Days to decision	183 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	97 submissions · 97 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	Yoshiaki Cook

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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