

**K252074 Aplio i900, Aplio i800 and Aplio i700 Software V9.0  
Diagnostic Ultrasound System**Oct 31, 2025  
121 days to decisionK252074 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k252074/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 2, 2025
Decision date	Oct 31, 2025
Days to decision	121 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, Inc.</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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k252074/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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