

K250328 UltraExtend NX CUW-U001S V2.0 Ultrasound Image Analysis Program

Apr 30, 2025
84 days to decisionK250328 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 5, 2025
Decision date	Apr 30, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Canon Medical Systems Corporation
Location	Otawara-Shi, JP
Contact	Orlando Tadeo Jr.
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...

REGULATORY CONSULTANT

Consulting firm	Canon Medical Systems USA, Inc.
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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Device record: <https://www.510kdatabase.net/k250328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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