

K251370 Cartesion Prime (PCD-1000A/3) V10.21Dec 1, 2025
213 days to decisionK251370 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k251370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	May 2, 2025
Decision date	Dec 1, 2025
Days to decision	213 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
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)
