

**K253560 Enhanced Boundary for PCCT**Jun 24, 2026  
219 days to decisionK253560 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k253560/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 17, 2025
Decision date	Jun 24, 2026
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems, LLC</b>
Location	Waukesha, WI, US
Contact	Veronica Aguayo
Website	<a href="https://www.gehealthcare.com">https://www.gehealthcare.com</a>
510(k) history	105 submissions · 105 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...

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