

K243605 AuroraJan 17, 2025
57 days to decisionK243605 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k243605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Nov 21, 2024
Decision date	Jan 17, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Israel, Functional Imaging
Location	Tirat Hacarmel, IL
Contact	Hanne Jubran
510(k) history	4 submissions · 4 cleared · 2010-2025

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