

K251153 AuroraJun 12, 2025
59 days to decisionK251153 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k251153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 14, 2025
Decision date	Jun 12, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Israel
Location	Tirat Hacarmel, IL
Contact	Hanne Jubran
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251153/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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