

K253649 Spectral CT Verida FamilyMar 27, 2026
127 days to decisionK253649 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k253649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 20, 2025
Decision date	Mar 27, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Technologies , Ltd.
Location	Haifa, IL
Contact	Siwar Assi
510(k) history	4 submissions · 4 cleared · 2018-2026

CLINICAL EVIDENCE - NCT07108205

Image Quality Study of Spectral Precise Image CT 7700

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	126 patients (actual)
Study sites	3 sites
Condition studied	Head; Body; Cardiac
Study type	Observational
Completion date	Oct 14, 2025
Sponsor	Philips Clinical & Medical Affairs Global (Industry)

Primary outcome

Image Quality (IQ) of Spectral Precise Image reconstructions non inferior to iDose conventional images

Secondary outcome

Evaluation of the differences in Image Quality (IQ) of Spectral Precise Image reconstructions versus iDose conventional images

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT07108205