

K253844 AnyScan 3.0 NM Scanner FamilyDec 30, 2025
28 days to decisionK253844 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k253844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 2, 2025
Decision date	Dec 30, 2025
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mediso Medical Imaging Systems, Ltd.
Location	Budapest, HU
Contact	Daniel Cser
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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