

K253023 BIOGRAPH OneJan 15, 2026
118 days to decisionK253023 · Product code: **OUO** · Radiology
Source: <https://www.510kdatabase.net/k253023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Sep 19, 2025
Decision date	Jan 15, 2026
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthineers AG
Location	Forchheim, DE
Contact	Friederike Hertle
Website	http://www.siemens.de/healthcare
510(k) history	3 submissions · 3 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Siemens Medical Solutions USA, Inc.
Contact	Alina Goodman

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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