FDA 510(k) Premarket Notification

K261315 Symbia Pro.specta Q3 (11364751)

CLEARED

May 21, 2026
30 days to decision

K261315 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k261315/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 21, 2026
Decision date	May 21, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Symbia Pro.specta X3 (11364752);Symbia Pro.specta X7 (11364753);Symbia Pro.specta VA40 Family

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	Tabitha Estes
510(k) history	779 submissions · 779 cleared · 1980-2026

REGULATORY CONSULTANT

Consulting firm	**Siemens Medical Solution USA, Inc.**
Contact	Tabitha Estes

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