

K231833 Biograph Vision.X and Biograph Vision.X EdgeJul 13, 2023
21 days to decisionK231833 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k231833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jun 22, 2023
Decision date	Jul 13, 2023
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Alaine Medio
510(k) history	778 submissions · 778 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231833/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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