

**K211247 PET VCAR**Jul 27, 2021  
92 days to decisionK211247 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k211247/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 26, 2021
Decision date	Jul 27, 2021
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GE Medical Systems SCS</b>
Location	Buc Cedex, FR
Contact	Elizabeth Mathew
510(k) history	37 submissions · 37 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211247/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026