

K001681 POSITRACE DUAL MODE PET/CT ONCOLOGY SYSTEMAug 25, 2000
85 days to decisionK001681 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k001681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jun 1, 2000
Decision date	Aug 25, 2000
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smv America
Location	Twinsburg, OH, US
Contact	FRANCOIS ROCHE
510(k) history	7 submissions · 7 cleared · 1997-2001

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