

**K010509 CEDARS-SINAI BPGS AND MOCO**Apr 27, 2001  
65 days to decisionK010509 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k010509/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Feb 21, 2001
Decision date	Apr 27, 2001
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Smv America</b>
Location	Twinsburg, OH, US
Contact	PAULA MCLEAN
510(k) history	7 submissions · 7 cleared · 1997-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010509/> 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 19, 2026