

**K043381 INFINIA LIGHTSPEED**Dec 23, 2004  
14 days to decisionK043381 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k043381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 9, 2004
Decision date	Dec 23, 2004
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems F.I. Haifa</b>
Location	Tirat Hacarmel, IL
Contact	LAURENCE BIGIO
510(k) history	17 submissions · 17 cleared · 1998-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043381/> 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 27, 2026