

**K050815 XACT.CARDIAC & XPRESS.CARDIAC**Apr 26, 2005  
26 days to decisionK050815 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k050815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Mar 31, 2005
Decision date	Apr 26, 2005
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultraspect , Ltd.</b>
Location	Haifa, IL
Contact	DAN LAOR
510(k) history	6 submissions · 6 cleared · 2004-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050815/> 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 17, 2026