

**K040616 CARDIOMD-AC**Mar 24, 2004  
15 days to decisionK040616 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k040616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Mar 9, 2004
Decision date	Mar 24, 2004
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Danish Diagnostic Development A/S</b>
Location	2970 Horshom, DK
Contact	NIELS SORENSEN
510(k) history	6 submissions · 6 cleared · 2000-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040616/> 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 18, 2026