

**K970970 CARDIOMATCH**Jun 13, 1997  
88 days to decisionK970970 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k970970/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Mar 17, 1997
Decision date	Jun 13, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focus Medical SA</b>
Location	Wellesley, MA, US
Contact	JEAN-LUC BOULNOIS
510(k) history	1 submissions · 1 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970970/> 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 20, 2026