

**K072950 CYGNUS 12 LEAD ECG MODULE**Aug 22, 2008  
309 days to decisionK072950 · Product code: **KRE** · CardiovascularSource: <https://www.510kdatabase.net/k072950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Oct 18, 2007
Decision date	Aug 22, 2008
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cygnus, LLC</b>
Location	Paterson, NJ, US
Contact	NARCIS NAYDENOV
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072950/> 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 June 24, 2026