

**K863231 D100 COMPUTER CARDIAC ANALYSIS SYSTEM**Nov 25, 1986  
96 days to decisionK863231 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k863231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Aug 21, 1986
Decision date	Nov 25, 1986
Days to decision	96 days
Third-party review	No

**APPLICANT**

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Company	<b>Dextra Medical, Inc.</b>
Location	Long Beach, CA, US
Contact	SLAWOMIR LOBODZINSKI
510(k) history	2 submissions · 2 cleared · 1986-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863231/>; 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 July 7, 2026