

**K862808 BIOMA 2000**Feb 19, 1987  
211 days to decisionK862808 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k862808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Jul 23, 1986
Decision date	Feb 19, 1987
Days to decision	211 days
Third-party review	No

**APPLICANT**

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Company	<b>E.B.S., Inc.</b>
Location	Canada, CA
Contact	SYLVAIN BOUCHER
510(k) history	3 submissions · 3 cleared · 1987-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862808/>; 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