

**K935839 GEMSCOM SERIES 5000,**Nov 10, 1994  
338 days to decisionK935839 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k935839/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Dec 7, 1993
Decision date	Nov 10, 1994
Days to decision	338 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>General Devices</b>
Location	Bergenfield, NJ, US
Contact	MICHAEL SMITH
510(k) history	13 submissions · 13 cleared · 1983-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935839/> 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 30, 2026