

**K101078 BL HEALTHCARE REMOTE CARE MANAGEMENT SYSTEM**May 10, 2010  
21 days to decisionK101078 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Apr 19, 2010
Decision date	May 10, 2010
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BI Healthcare, Inc.</b>
Location	Foxboro, MA, US
Contact	MICHAEL MATHUR
510(k) history	5 submissions · 5 cleared · 2005-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101078/> 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 15, 2026