

**K100315 12 LEAD GLOVE**Apr 23, 2010  
78 days to decisionK100315 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k100315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 4, 2010
Decision date	Apr 23, 2010
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>I Needmd, Inc.</b>
Location	New York, NY, US
Contact	IRVING L WIESEN, ESQ
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100315/> 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 21, 2026