

**K031174 BODY SIGNAL ECG ELECTRODE**Jul 10, 2003  
87 days to decisionK031174 · Product code: **DRX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031174/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Apr 14, 2003
Decision date	Jul 10, 2003
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Wandy Rubber Industrial Co., Ltd.</b>
Location	Shi-Chih, Taipei, TW
Contact	JANIS YANG
510(k) history	4 submissions · 4 cleared · 2001-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031174/> 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 7, 2026