

**K950471 DISPOSABLE ECG MONITORING ELECTRODE #4580  
32X45MM**Nov 6, 1995  
276 days to decisionK950471 · Product code: **DRX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k950471/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 3, 1995
Decision date	Nov 6, 1995
Days to decision	276 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nikomed U.S.A., Inc.</b>
Location	Belle Mead, NJ, US
Contact	DONALD C EPSTEIN
510(k) history	15 submissions · 15 cleared · 1987-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950471/> 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 May 26, 2026