

**K944497 UNILECT, MONITAB AND BIOTRACE-HR**May 17, 1996  
612 days to decisionK944497 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k944497/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Sep 13, 1994
Decision date	May 17, 1996
Days to decision	612 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Msb , Ltd.</b>
Location	Marlborough, Wiltshire, GB
Contact	MARTIN BEAUMONT
510(k) history	7 submissions · 7 cleared · 1994-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944497/> 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