

**K864989 ETP 180A NON-INVASIVE EXTERNAL PACEMAKER**Mar 3, 1987  
71 days to decisionK864989 · Product code: **DRO** · CardiovascularSource: <https://www.510kdatabase.net/k864989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Dec 22, 1986
Decision date	Mar 3, 1987
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>Medac, Inc.</b>
Location	Tualatin, OR, US
Contact	ROBERT M BOONSTRA
510(k) history	10 submissions · 10 cleared · 1987-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864989/>; 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 July 7, 2026