

K864988 ETP 180E NON-INVASIVE EXTERNAL PACEMAKERMar 3, 1987
71 days to decisionK864988 · Product code: **DRO** · Cardiovascular
Source: <https://www.510kdatabase.net/k864988/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864988/>; Data sourced from FDA 510(k) public records (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. - Generated July 7, 2026