FDA 510(k) Premarket Notification

K874090 300M ECG MONITRO/TRANSCUTANEOUS PACEMAKER

CLEARED

Dec 15, 1987
69 days to decision

K874090 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k874090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Oct 7, 1987
Decision date	Dec 15, 1987
Days to decision	69 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