

K885166 ZMI PART NO. NTP-2100, PEDIATRIC ELECTRODESMay 1, 1989
139 days to decisionK885166 · Product code: **DRO** · Cardiovascular
Source: <https://www.510kdatabase.net/k885166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Dec 13, 1988
Decision date	May 1, 1989
Days to decision	139 days
Third-party review	No

APPLICANT

Company	Zmi Corp.
Location	Cambridge, MA, US
Contact	PAUL A LEVESQUE
510(k) history	8 submissions · 8 cleared · 1986-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k885166/>; 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 1, 2026