

K915328 GEL-TACJun 29, 1992
216 days to decisionK915328 · Product code: **DRO** · Cardiovascular
Source: <https://www.510kdatabase.net/k915328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Nov 26, 1991
Decision date	Jun 29, 1992
Days to decision	216 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Katecho, Inc.
Location	Des Moines, IA, US
Contact	LORNE SCHARNBERG
510(k) history	26 submissions · 25 cleared · 1984-2001

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