

**K012218 LUDLOW GRADIENT EDGE ADULT & PEDIATRIC
MULTIFUNCTIONAL ELECTRODES**Oct 12, 2001
88 days to decisionK012218 · Product code: **DRO** · Cardiovascular
Source: <https://www.510kdatabase.net/k012218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Jul 16, 2001
Decision date	Oct 12, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Ludlow Company LP
Location	Chicopee, MA, US
Contact	KATHLEEN M TREMBLAY
510(k) history	3 submissions · 3 cleared · 2001-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012218/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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