FDA 510(k) Premarket Notification

K882338 MODEL #716 ADULT STIM. PADS LOW IMPEDANCE GEL TYPE

CLEARED

Aug 30, 1988
85 days to decision

K882338 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k882338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Jun 6, 1988
Decision date	Aug 30, 1988
Days to decision	85 days
Third-party review	No

APPLICANT

Company	**Cardiotronics, Inc.**
Location	West Carlsbad, CA, US
Contact	TIM J WAY
510(k) history	27 submissions · 27 cleared · 1988-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k882338/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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