FDA 510(k) Premarket Notification

K850791 MDI 2000 - PULSE GENERATOR

CLEARED

Jun 19, 1985
113 days to decision

K850791 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k850791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Feb 26, 1985
Decision date	Jun 19, 1985
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Micromedical Devices, Inc.**
Location	Mchenry, IL, US
Contact	KAREN MURPHY
510(k) history	7 submissions · 7 cleared · 1984-2004