FDA 510(k) Premarket Notification

K854175 DEFIGARD 2000

CLEARED

Jan 13, 1986
90 days to decision

K854175 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k854175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Oct 15, 1985
Decision date	Jan 13, 1986
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Odam**
Location	Mchenry, IL, US
Contact	CANSELL
510(k) history	6 submissions · 6 cleared · 1983-1998