FDA 510(k) Premarket Notification

K912587 K-FREE

CLEARED

Jul 30, 1991
48 days to decision

K912587 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k912587/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Jun 12, 1991
Decision date	Jul 30, 1991
Days to decision	48 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