FDA 510(k) Premarket Notification

K823931 DEFIGARD M(OR DEFISCOPE M

CLEARED

Apr 12, 1983
104 days to decision

K823931 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k823931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Dec 29, 1982
Decision date	Apr 12, 1983
Days to decision	104 days
Third-party review	No

APPLICANT

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