FDA 510(k) Premarket Notification

K970481 V2

CLEARED

Jul 1, 1997
141 days to decision

K970481 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k970481/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Feb 10, 1997
Decision date	Jul 1, 1997
Days to decision	141 days
Third-party review	No

APPLICANT

Company	**Survivalink Corp.**
Location	Minnetonka, MN, US
Contact	SEW-WAY TAY
510(k) history	7 submissions · 5 cleared · 1995-2002