FDA 510(k) Premarket Notification

K821152 HEART AID #90

CLEARED

Aug 6, 1982
102 days to decision

K821152 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k821152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Apr 26, 1982
Decision date	Aug 6, 1982
Days to decision	102 days
Third-party review	No

APPLICANT

Company	**Cardiac Resucitator Corp.**
Location	Mchenry, IL, US
510(k) history	17 submissions · 16 cleared · 1981-1988