FDA 510(k) Premarket Notification

K954551 DF-1 TERMINAL CAP

CLEARED

Dec 26, 1995
85 days to decision

K954551 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k954551/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Oct 2, 1995
Decision date	Dec 26, 1995
Days to decision	85 days
Third-party review	No

APPLICANT

Company	**Pacesetter, Inc.**
Location	Sylmar, CA, US
Contact	JACQUELINE J JACKSON
510(k) history	8 submissions · 2 cleared · 1995-1998