FDA 510(k) Premarket Notification

K954714 AFP CARDIAC PACING SYSTEM MODEL 283 (MODIFICATION)

CLEARED

Feb 1, 1996
122 days to decision

K954714 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k954714/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Oct 2, 1995
Decision date	Feb 1, 1996
Days to decision	122 days
Third-party review	No

APPLICANT

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