

**K951950 PASSIVE PLUS PACING LEADS WITH TITANIUM
NITRIDE COATING**Aug 31, 1995
127 days to decisionK951950 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k951950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Apr 26, 1995
Decision date	Aug 31, 1995
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951950/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026