

K972814 LOCATOR MODEL 4036Feb 23, 1998
209 days to decisionK972814 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k972814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 29, 1997
Decision date	Feb 23, 1998
Days to decision	209 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972814/>; 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