

**K912507 CPI MODEL 2215 & SEAMED MODEL 3400**Sep 3, 1991  
89 days to decisionK912507 · Product code: **DTE** · CardiovascularSource: <https://www.510kdatabase.net/k912507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jun 6, 1991
Decision date	Sep 3, 1991
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Seamed Corp.</b>
Location	Walker, MI, US
Contact	MARCIA A PAGE
510(k) history	18 submissions · 18 cleared · 1982-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912507/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 6, 2026