

**K854648 SEAMED MODEL 4000**Jan 16, 1986  
58 days to decisionK854648 · Product code: **DTE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k854648/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Pulse-generator, Pacemaker, External (DTE) |
| Date received         | Nov 19, 1985                               |
| Decision date         | Jan 16, 1986                               |
| Days to decision      | 58 days                                    |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Seamed Corp.</b>                     |
| Location       | Walker, MI, US                          |
| Contact        | DAN ROPER                               |
| 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/k854648/>; 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