

**K832245 UNIPOLAR-E ENDOCARDIAL TINED LEAD**Aug 12, 1983  
32 days to decisionK832245 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k832245/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received         | Jul 11, 1983                        |
| Decision date         | Aug 12, 1983                        |
| Days to decision      | 32 days                             |
| Third-party review    | No                                  |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Cook Pacemaker Corp.</b>             |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 34 submissions · 31 cleared · 1981-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k832245/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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