

**K874205 ENDOCARDIAL SCREW-IN LEAD, MODEL 1018T**Feb 2, 1988  
110 days to decisionK874205 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k874205/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received         | Oct 15, 1987                        |
| Decision date         | Feb 2, 1988                         |
| Days to decision      | 110 days                            |
| Third-party review    | No                                  |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Pacesetter Systems</b>               |
| Location       | Mchenry, IL, US                         |
| Contact        | RITA BROWN                              |
| 510(k) history | 96 submissions · 96 cleared · 1976-1991 |

Pacesetter Systems was a biotechnology company founded by Alfred E. Mann in 1965, headquartered in McHenry, US. The company pioneered implantable medical devices, including the first commercial rechargeable implantable pacemaker and early telemetry-enabled systems. Pacesetter Systems received FDA 510(k) clearances from total submissions between 1976 and 1991. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. This historical record reflects the company's core expertise in pacemaker technology, leads, adapters, and ...

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