

K831435 VENTRICULAR PACING LEADS MODELS 865/867Jun 8, 1983
35 days to decisionK831435 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k831435/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | May 4, 1983 |
| Decision date | Jun 8, 1983 |
| Days to decision | 35 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Pacesetter Systems |
| Location | Mchenry, IL, US |
| 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 ...