

**K891905 CARDIOVASCULAR PERMANENT PACEMAKER
ELECTRODE**Jun 5, 1989
70 days to decisionK891905 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k891905/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Mar 27, 1989 |
| Decision date | Jun 5, 1989 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Pacesetter Systems |
| 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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